Safe Laparoscopy in Low & Middle Countries

by reducing Surgical Site Infections through **Laparoscopic Instrument Cleaning**

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Executive Summary

Access to safe and affordable surgery is nothing short of a basic human right and people from all walks of life are entitled to it. However, even now, in the 21st century, only two of the seven billion people in the world are privileged enough to be supported by healthcare systems. Most people from resource-constrained low and middle-income countries are vulnerable and left to fend for themselves when they need for surgery is a life governing event. Due to the resource constraints in developing areas like rural India, inhabitants of these regions are scourged by low life expectancy and high mortality due to surgical infections. A majority of these infections are caused by the use of unclean and unsterile surgical instruments. A significant reduction in infections can be achieved by using clean and sterile surgical instruments

Minimally Invasive Surgery, in this case, Laparoscopy, is a promising technique of surgery developed to quickly and efficiently perform complex abdominal surgeries with the use of small and minimum incisions on the patient. Laparoscopy's minimally invasive nature allows complex surgeries to take place without the need of an absolutely sterile operating room, although the sterility of the surgical instruments cannot be compromised. The added benefit of faster recovery from smaller wounds makes it even more desirable for this context.

The Minimally Invasive Surgery and Interventional Techniques (MISIT) Lab is a research lab of the TU Delft that focuses on minimally invasive surgery. Some of the projects address the health and well-being of resource-constrained, underdeveloped communities like rural India through frugal innovation.

Rural Indian hospitals are grossly underfunded, under-maintained, and understaffed. Sterile processing practices in rural India are very rudimentary compared to the practices observed in high-income hospitals like the ones in the Netherlands.

In high-income hospitals, all used surgical instruments are cleaned and sterilized in dedicated central sterile processing departments (CSSD) by highly trained and well protected sterile processing technicians. However, rural India usually employs small teams of local undertrained and semi-literate nurses to carry out every primary and ancillary duty in the hospital. The lack of dedicated CSSDs exacerbates the nurse's workload and exposure to harmful pathogenic surgical instruments.

Laparoscopic instruments developed in high-income nations are seldom designed keeping low resource contexts in mind. The geometrical complexity of instruments keeps increasing but cleaning methods in rural India have stagnated. Resource constraints are a major reason as to why proper international and national guidelines for reprocessing cannot be followed. Hence hospitals cannot guarantee 100% safe and sterile instruments as compared so standardized outcomes in high-income hospitals.

In this graduation project, the distinct reprocessing journey of surgical instruments for the two seemingly diverse economic contexts were studied. A comparative analysis of both reprocessing journeys uncovered severe unsafe and unfavorable practices in rural India. Significant data and insights from the research have hence paved the way for focusing on the "Cleaning" stage of the laparoscopic instrument reprocessing journey in rural India.

This MSc graduation project aims at designing a frugal solution for cleaning and repurposing laparoscopic instruments, dedicated to hospitals in rural India where the demand for laparoscopy is high but surgeries are less due to resource constraints like lack of laparoscopic instruments and repurposing devices.

The involvement of an Indian nurse and laparoscopic surgeon provided much needed first-hand information about the problems and requirements in the rural Indian context. Prototyping and testing of various cleaning setup were conducted to extract the most viable design solution.

Insights from the research, prototyping, and testing were combined into the concept design of a frugal mechanical washer and subsequently an "Envisioned Reprocessing Journey" for rural Indian hospitals to suggest a standard protocol for keeping most of their existing infrastructure in mind.

Evaluations with the Indian nurse revealed that this device could indeed be a game-changer to the existing practices of reprocessing laparoscopic instruments in rural India.

Abbreviations

MIS : Minimally Invasive Surgery

LMIC : Low and Middle Income Countries

HIC : High Income Countries

HI : High Income

MISIT : Minimally Invasive Surgery and Interventional Techniques

SSI : Surgical Site Infections

HCAI : Healthcare Associated Infections

OR : Operation Room

CSSD : Central Sterile Supply Department

SPD : Sterile Processing Department

UN : United Nations

SDG : Sustainable Development Goals

RSI : Reusable Surgical Instruments

RLSI : Reusable Laparoscopic Surgical Instruments

DALY : Disability Adjusted Life Years

MRI : Magnetic Resonance Imaging

CT : Computed Tomography

WHO : World Health Organization

RPM : Revolutions per minute

Contents

1 Introduction

1.1 Introduction

This graduation project is a part of Ph.D. candidate ir. Daniel Robertson's research project: SMART Surgical Systems focusing on making minimally invasive surgery (MIS) like laparoscopy applicable in low resource countries. Laparoscopy is now a widely accepted method of surgery in all hospital contexts, however, a plethora of barriers challenge it's implementation in low and middle-income countries (LMIC) like rural India. This project in collaboration with the TU Delft Faculty of Industrial Design Engineering, the TU Delft Biomedical Engineering Department, and hospitals in rural India is an initiative under the TU Delft MISIT Lab (Minimally Invasive Surgery and Interventional Techniques) lab which focuses on finding solutions to worldwide problems in areas of surgery and healthcare.

One such lamenting global problem is access to safe and affordable surgery. Even with great strides taken in the field of healthcare, safe surgical practices have been an overlooked factor. The progress has been lopsided with vast improvements in high-income countries (HIC), leaving the low-middle income countries (LMIC) deprived of this progress (Meara, J.G et al. 2016).

The global shift in healthcare priorities to tackle trending communicable diseases like HIV, ebola, COVID19 and malaria has contributed to ignoring the problem of safe surgery. Significant barriers like unstable national healthcare systems, high equipment costs, complex design of surgical equipment, unsterile surgical instruments and operating rooms (OR), lack of training and awareness of healthcare-associated infections (HCAIs) are some of the reasons for high morbidity rates in surgery patients in LMICs (Ohara et.al 2015).

Implementation of minimally invasive surgery (MIS) is a proven method of minimizing healthcare-associated infections (HCAI) (Chao et.al 2015). Laparoscopy is a method of MIS that addresses issues pertaining to surgery of the abdominal cavity. Specialized surgical "by using sterile surgical instruments devoid of pathogens, bodily fluids, bioburden and maintaining safe and sterile reprocessing practices, laparoscopic surgery in rural India can effectively reduce morbidity and mortality rates even more. "

instruments are inserted into the patient through small incisions, thus reducing the patient's recovery time, scarring, bleeding, perioperative infections, and costs by allowing the patient to be discharged in considerably less time as compared to open surgeries. Hence could be a logical method of surgery for rural India where patients, in many cases daily wage workers, cannot afford health care and hospitalization costs.

Despite the advantages of laparoscopy, the surgical mortality rate in rural India is extremely high (Jamir et.al. 2015). There is very little statistical information about laparoscopic surgery in India in terms of surgical infections and deaths (Chao et al. 2015; Jamir et al. 2015). The WHO aims to alleviate the problem of surgical site infections (SSI) in LMICs by 2030 under the United Nations Sustainable Development Goals 2030 (UN SDG). Yet in 2020, millions of Indians are plagued with SSIs due to unacceptable surgical practices.

Considering the nature and practice of laparoscopy, the multiple components of the laparoscopic instruments makes it difficult to reach tighter/ small areas, making them inherently difficult to reprocess, favoring the formation of pathogenic colonies (Lopes et al.2019). Rural Indian hospitals do not have the necessary means to reprocess soiled laparoscopic surgical instruments efficiently. The lack of proper reprocessing practices, central sterile services departments (CSSD), low funds, lack of trained sterile processing technicians lead to the use of dirty and unsterile laparoscopic instruments. These unsterile surgical instruments pose a major risk of SSI outbreaks in this context.

Therefore, by using sterile surgical instruments devoid of pathogens, bodily fluids, bioburden, and maintaining safe and sterile reprocessing practices, laparoscopic surgery in rural India can effectively reduce morbidity and mortality rates even more.

1.2 Field Research

To understand the context of the project, a field trip to four rural Indian hospitals was conducted by ir. Daniel Robertson in March 2020. Visiting these hospitals was crucial to help create detailed cleaning journeys of surgical instruments and break down every step of the journey to its core components to identify voids and malpractices as compared to the WHO's guidelines. Journey mapping is an extremely important tool and has been used multiple times in this project to systematically assess the field research. Qualitative research with field observations and interviews with surgeons and nurses in rural Indian hospitals provided valuable first hand insights into the conditions of rural Indian hospital ORs and sterile processing facilities.

Reprocessing practices in HICs are considered as standard procedures as per WHO guidelines. Chapter 4.2 describes the standard procedure in detail. In order to make a comparative study between instrument reprocessing practices in HIC and LMIC hospitals, a field visit to LUMC Leidens Central Sterile Supply Department (CSSD) was conducted.

The Indian field research revealed that rural Indian hospitals are severely underfunded, understaffed, have under trained nurses and lack even the most basic equipment for effectively reprocessing surgical instruments. Surgical infrastructure and instrument reprocessing practices are severely suboptimal and primitive in the given context.

1 . 3 Challenge

"It is necessary to have design interventions that are coherent with the context and resource availability"

With the advent and adoption of complex laparoscopic surgical instruments capable of performing even more complex surgeries, the problem of reprocessing these instruments still remains to be an under-addressed factor for surgical safety and curbing SSIs. Most (laparoscopic) instruments are developed in HICs (Malkin et al. 2007), focusing on the top of the pyramid context, leaving the resource-constrained bottom pyramid contexts like rural India to fend for themselves. Hence implementing these devices and coinciding reprocessing practices in LMICs would result in unfavorable outcomes.

It is necessary to have design interventions that are coherent with the context and resource availability. When designing a new piece of equipment or process, the limiting contextual factors should also be taken into account. Rural hospitals seem to value cost and simplicity. Therefore, for a new piece of equipment or a new standard operating procedure to be accepted, the factors like cost, user-friendly design, robustness, etc should be a leading design requirement (interview).

Gnanaraj Jesudian's paper on the feasibility and issues related to performing laparoscopic surgeries in rural areas is a perfect reflection of the challenges in performing laparoscopic surgeries in the backward regions of India (Jamir et al. 2015). Indian medical professionals have positively accepted laparoscopy but cannot afford to perform them due to high ancillary costs. To keep costs to a minimum, rural doctors are known to reuse disposable laparoscopic instruments by attempting to re-sterilize them multiple times but without any conventional and accepted methods (Jamir et al. 2015). For this reason, the use of disposables exacerbates the risks of infections. High Infection rates in rural India can be attributed to the unsterile and unhygienic conditions of the operating rooms, estrangement from guidelines, and unavailability of basic sterilizing equipment and trained sterile processing technicians.

The advancements in laparoscopic surgery in HICs are not compatible with the current reprocessing practices in rural India and hence fail.

The challenge of this project is to identify the gaps and malpractices in the existing reusable laparoscopic surgical instrument reprocessing journeys in rural Indian hospitals and comparing it to the standard operating procedures of the HIC hospitals. A design intervention is further proposed based on the identified gaps. This comparison is necessary to find opportunities and design interventions to fill the voids in the low-income hospital context's reprocessing practices to ensure the cleaning of reusable laparoscopic instruments.

1 . 4 Project Scope

"the scope of the project is focused on the "Cleaning" stage of laparoscopic instrument reprocessing in rural Indian hospitals.

The focus of the project is to reduce surgical site infections (SSIs) caused by laparoscopic surgeries in rural Indian hospitals by addressing and improving instrument reprocessing practices. This is done to ensure the laparoscopic instruments are clean and sterile before their next use cycle.

Laparoscopy is performed with special laparoscopic instruments in addition to general surgical tools. Even though general surgical tools are out of the scope, it is necessary to address them due to the lack of information regarding Indian laparoscopic instrument reprocessing practices in specific.

Through the performed context observations and thorough instrument reprocessing journeys, the scope of the project is focused on the "Cleaning" stage of laparoscopic instrument reprocessing in rural India.

The scope is shaped by the initial desktop research and literature wherein cleaning is considered the most important step of the reprocessing journey and if not adequate, may contribute to the pathogenic formation (Lopes et.al 2019) as sterilization without cleaning is not possible.

1.5 Project Goal

After exploring the challenges of reprocessing reusable laparoscopic surgical instruments in the context of rural Indian hospitals, the goals for this graduation project are:

1. to conceptualize a minimal viable device that is robust, familiar, frugal, cost-effective, and user-friendly focusing on the mechanical washing stage of the laparoscopic reprocessing journey. This device should be used by under-trained ancillary staff and nurses in low and middle-income hospitals in India with confidence and ease, so as to prevent these members from needlessly exposing themselves to dangerous unsterile surgical instruments.

2. to create a new instrument cleaning journey called the "Envisioned Instrument Reprocessing Journey" for rural India. This journey is created by combining and analyzing the safety and procedural gaps in the comparisons observed between HIC and LMIC hospital practices.

2 Surgery & Safety

The discovery phase of this graduation project is to have a rich, qualitative exploration of the rural Indian context to identify current reprocessing practices, the challenges to be tackled in the low resource context, limitations, and recognize important voids as design directions.

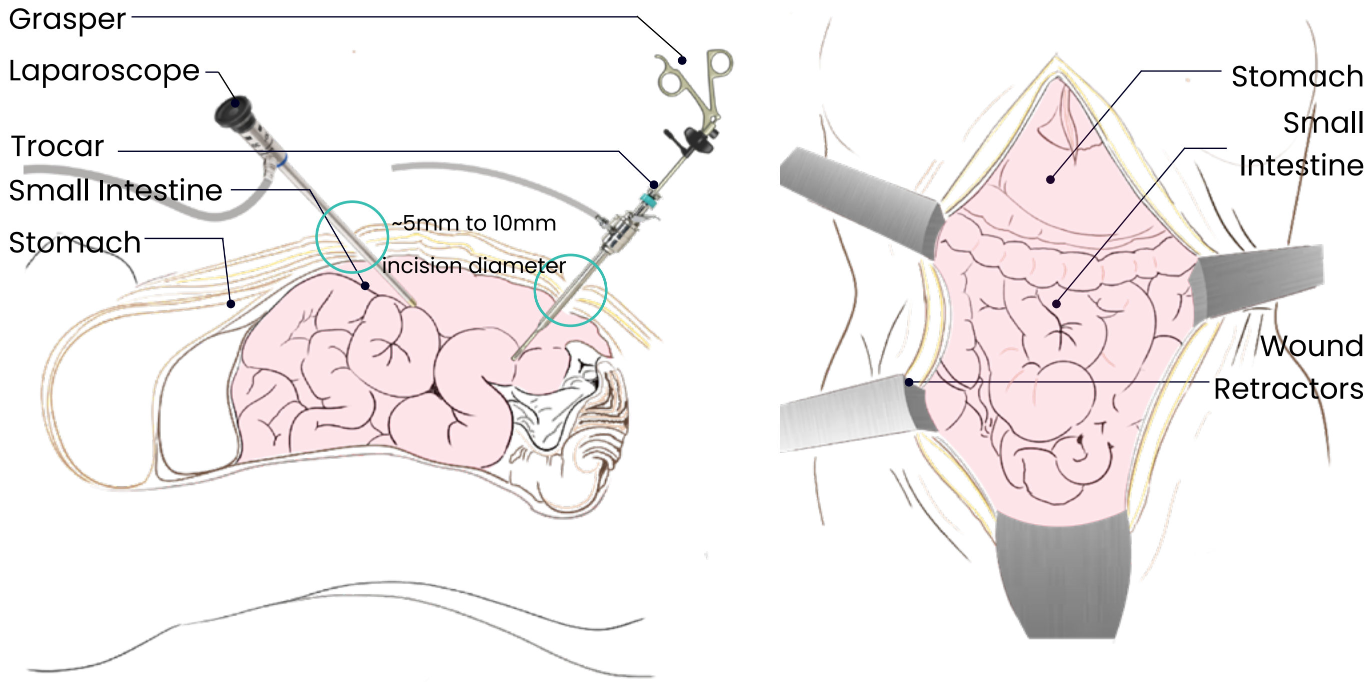
Literature research consisted of understanding the entire process of general laparoscopic surgery, surgical instruments, instrument reprocessing guidelines set by WHO and CDC, global SSI statistics, and in-depth exploration into every step of surgical instrument reprocessing in HIC and LMIC hospitals.

Qualitative context exploration included understanding the rural Indian healthcare system, field visits to LUMC Leiden, four rural Indian hospitals, and interviews with rural surgeons and nurses.

2.1 Laparoscopy in LMICs.

The advent of laparoscopy in India began in the 1980s (Udwadia 2015) to reduce postoperative mortality and improve the orthodox laparotomic procedures where surgeons would make larger incisions for direct tactile access to the patient's organs. Through traditional laparotomy, the perioperative and postoperative infections are considerably higher due to the large incisions made to allow the access of surgical instruments. Complications that arise due to these infections are financially detrimental to patients, demanding higher healthcare costs, and risk of mortality. Fig 2.1.1 illustrates the comparisons between laparotomy and laparoscopy.

Due to laparoscopy's minimally invasive nature, the use of small incisions to insert trocars and graspers heal faster, reduce risks of infection, bleeding, post-operative pain, and scarring, thus reducing the dependence of pain medication. The quick recovery speed allows early discharge helping the patient to minimize healthcare costs, frees up hospital beds, and reduces the need for painkillers and antibiotics which are an added expense to the already poor patients (fig 2.2.2).



LAPAROSCOPIC PROCEDURE
SAGITTAL CUT AWAY VIEW OF THE INTESTINES

LAPAROTOMIC PROCEDURE
ANTERIOR VIEW OF THE INTESTINES FROM A MID-LINE INCISION

2.1.1 Difference between Laparoscopy and Laparotomy

Many LMIC households only have a single wage earner (Chao et al. 2015). Absence from work due to long periods of hospitalization directly translates to the added financial burden (Wali et al. 2017) due to lost wages proving to be financially disastrous to the patient.

Laparoscopy reduces the dependence of sterile operating rooms which is difficult to achieve and maintain in low resource settings. The rate of perioperative mortality with laparoscopy is 5% to 10% in LMICs compared to 0.4%-0.8% in HICs (Chao et al.2015). This difference in mortality between the aforementioned settings is because HICs prefer to treat coinciding conditions with laparoscopy.

Although the cost-effectiveness of diagnostic laparoscopy (DL) is evident, only 20% of the world's population has access to it (Udwadia 2004). Many consider laparoscopic surgery to be unsafe for low resource settings due to barriers like underdeveloped surgical infrastructure, high instrument costs, and absence of sterile processing in rural regions (Adisa et al. 2013; Choy et al. 2013). Great strides to improve surgical standards in LMICSs are yet to be taken (Nagral 2017).

Even with marginal resources, technical and logistical challenges, the demand for laparoscopy has been gradually increasing in LMICs as many benefits outweigh its drawbacks and bring immeasurable advantages to the patients, thus reducing operative mortality.

For the reasons mentioned in this chapter, it is clear that the adoption of laparoscopy in LMICs is only going to strengthen the developing world.

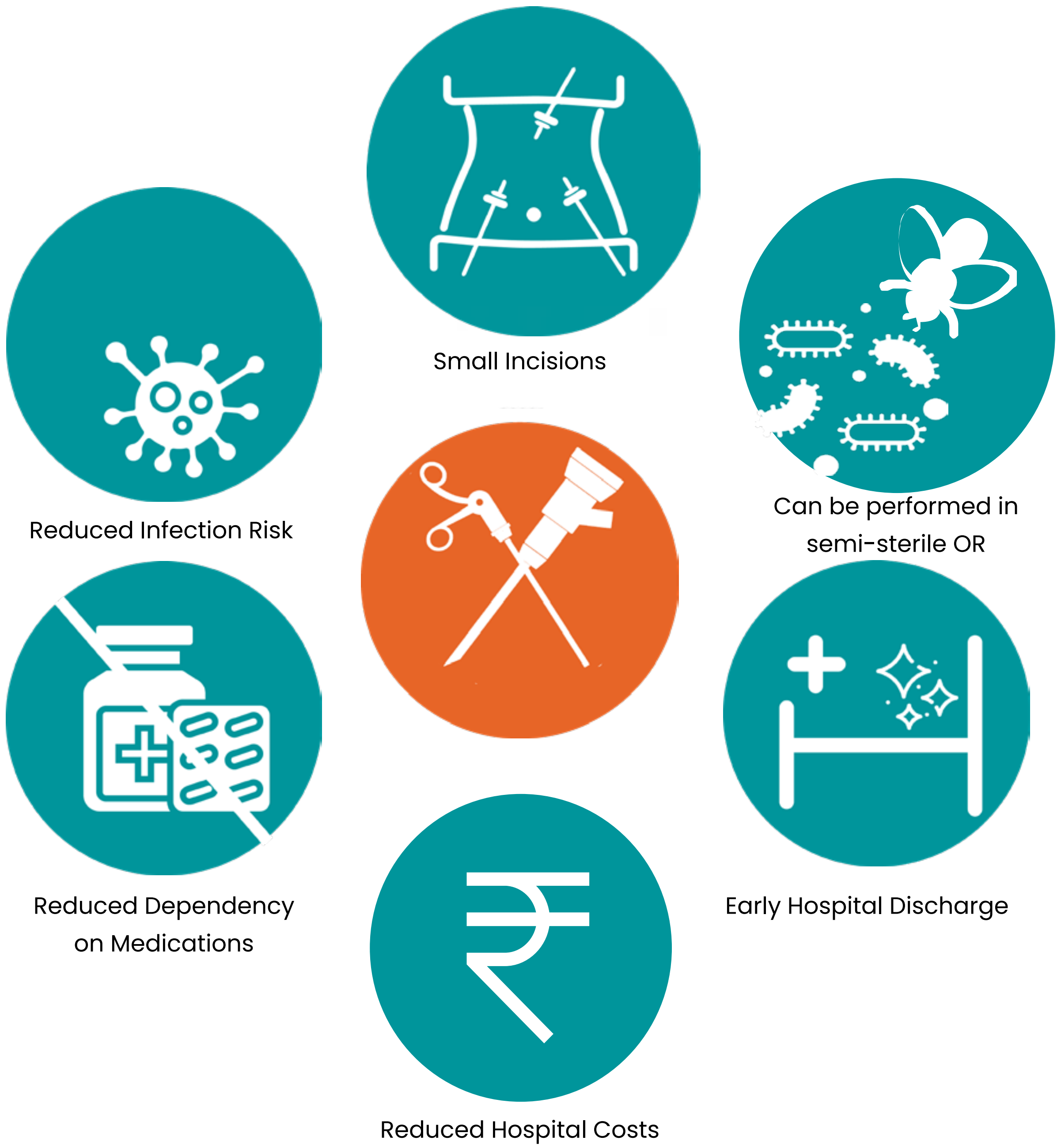


fig 2.2.2 Benefits of Laparoscopic surgery for the patient

2 . 2 Understanding the Laparoscopic Instruments.

The goal of this section is to get a basic understanding of laparoscopic surgical instruments in the scope of this graduation project. Instrument species, their geometrical complexity, pain points during reprocessing and methods needed to clean these instruments are explored. These features pose significant challenges to reprocess laparoscopic instruments. In this section, various regions of the laparoscopic instruments that are difficult to reach, collect most contaminants and pose difficulty for reprocessing are mapped. Mapping and identifying these hot-spots is crucial to develop design ideas that focus on these zones. The mapping is done on a scale from red to blue where red is the most critical region and blue is the least critical and easiest to clean.

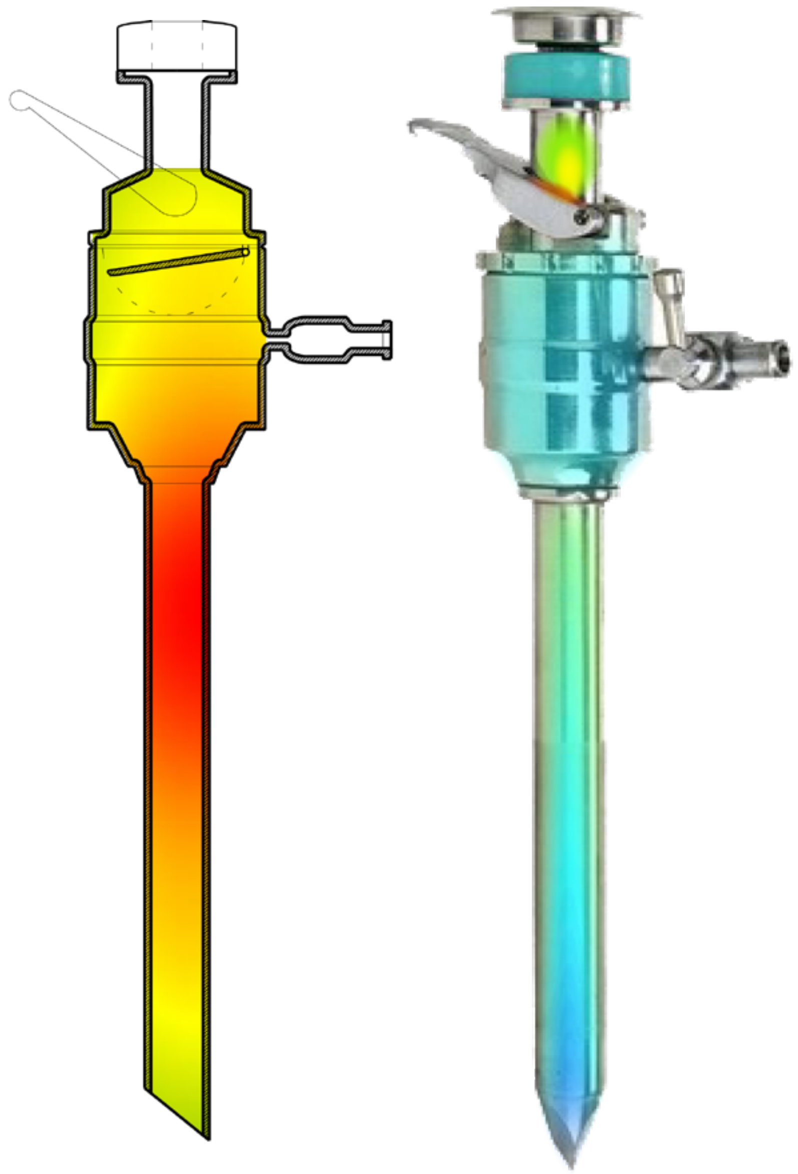
Laparoscopic surgical equipment are categorized into four groups:

1. Access Instruments

Trocars are the access instruments used to create minimally invasive access points through the patient's abdominal wall in order to insert scopes and graspers (fig 2.2.1). Commonly used trocars measure to a length of 180mm to 200mm and diameters of 5mm, 10mm, 12mm, 15mm. These trocars act as a gateway to all instruments inserted through it by preventing the carbon dioxide from leaking out of the cavity of the trocar, thus maintaining leakless pneumoperitoneum.

Pain Points

- The long and slender build of the trocar tube could harbor pathogenic deposits making them difficult to reprocess and inspect visually.
- The trocar's carbon dioxide trap doors (fig 2.2.2) are characterized by a moving metal flap hinged and attached to springs. Although visually accessible, cleaning the debris attached to the spring and trap door mechanism is tedious.



2.2.1 Contaminant collection and cleaning painpoint mapping on a reusable 10mm diameter trocar

Fig 2.2.2 Dismantled Trocar Trapdoor spring

2. Optical Instruments

Laparoscopes are the long and slender cameras inserted into the incisions to allow laparoscopic visibility for the surgeon. The cameras optimize the resolution of the surgical site. Laparoscopes are the easiest instruments to clean but cannot be ultrasonically cleaned and sterilized by conventional autoclaving due to delicate lenses and electronics.

Pain Points

- Laparoscopes are delicate instruments and need to be handled with care.
- Due to delicate lenses, laparoscopy cannot be sterilized by standard steam autoclaving.
- Laparoscopes cannot be cleaned with conventional ultrasonic cleaning and demand the use of special cleaning systems.

3. Operative Instruments

The operative instruments are the working ends of the surgeon inside the patient's body. These are the instruments that are in direct contact with tissues and organs. Examples of these instruments are graspers, clip applicators, bipolar graspers for electrosurgery and endoflex

Pain Points

- Dismantlable grasper sheaths are tubes ~300mm long with 5mm - 10mm diameter. This long and slender build hampers manual cleaning and visual inspection. Fluids and tissue are easily collected here. (fig 2.2.3).
- Cleaning these instruments is specially tedious due to their small crevices and long and slender build (fig 2.2.4).

Fig 2.2.3 Contaminant collection and cleaning painpoint mapping on reusable graspers.

Fig 2.2.4 Contaminant collection and cleaning painpoint mapping on a reusable steel clip applicator.

4. Supporting Equipment.

Supporting equipment is required for the laparoscopic surgery to take place. Irrigation and suction instruments are used for sucking away fluids from the surgical site for clear visibility.

Insufflation devices to help achieve pneumoperitoneum, light sources to insert inside the surgical site and high definition screens for surgeon's view into the surgical site are omnipresent aspects of laparoscopic surgery. Except for the irrigation instruments, all other mentioned devices are out of scope for this project because the aforementioned devices are not in direct contact with the operation table. Irrigation devices are inserted into the patient's wound to extract or irrigate fluids.

2 . 3 Infections due to Unsterile Surgical Conditions in LMICs.

There is a stark difference between the adoption of surgical instrument reprocessing practices of hospitals in HICs and LMICs. In HICs surgical instruments are reprocessed by adhering to strict guidelines in dedicated Central Sterile Supply Departments (CSSD). Operation rooms (OR) and CSSDs in HIC hospitals are observed to be far more superior than in their LMIC counterparts. This can be attributed to poor infrastructure, insufficient equipment, absence of adherence to guidelines, inadequate hygiene, and untrained staff in LMICs(Bardossy et al.2016). Fig 2.3.1 gives a clear idea of the aforementioned differences between HIC OR (top) and LMIC OR (bottom) where the former is observed to be well equipped with dedicated devices and a clean or almost sterile OR. The latter however hints at a more primitive low-cost OR setup that does not guarantee a high degree of sterilized environment.

Fig 2.3.1 Comparitive images of HIC Hospital (top) and LMIC Hospital (bottom).

"SSIs can be considered nothing short of a widespread pandemic and need to be tackled as one"

The demand for safe surgery in LMICs has increased so tremendously that advances in safe surgical procedures have not been able to keep up. Due to this imbalance, the safe monitoring of Health-care Associated Infections (HCAI) is almost unavailable in LMIC hospitals (Bardossy et al. 2016).

Healthcare-Associated Infections (HCAI) are caused due to hospital negligence and spread when patients are admitted to hospitals. Surgical Site Infections (SSI) are one such HCAI that are caused during surgeries and up to a month after (Owens et al. 2008). SSIs account for 38% of all HCAIs and affect at least one-third of the surgical patient population, potentially affecting millions (Braun 2016). The prevalence and frequency of SSIs in LMICs are three times higher as compared to HICs (Udwadia 2018). SSIs are a potential cause for long-term postoperative hospital admittance. Due to unhygienic surgical instruments, practices, a general lack of knowledge, and adherence to guidelines of rural Indian hospitals, tracing the source of SSI outbreaks is difficult. With the aforementioned global statistics of postoperative morbidity, SSIs can be considered nothing short of a widespread pandemic and need to be tackled as one.

2 . 4 Causes of SSIs

The most common constraints in LMICs are unsterile ORs, improper surgical techniques, complex design of surgical instruments and improperly repurposed surgical tools, financial and understaffed and undertrained staff. All these factors put together are the catalysts to needless suffering and increased healthcare costs and morbidity in LMICs (O'Hara 2015).

Infection outbreaks are related to the methods and practices hospitals undertake while reprocessing instruments, harboring traces of visible or/and invisible pathogens called bioburden from previous surgeries.

Bioburden can be eliminated by proper cleaning, disinfection and sterilization of instruments. It is important to rid the instruments off all bioburden and check the instruments thoroughly before sterilizing them for the next use cycle. However, sterility is not only difficult to maintain but also to ensure in LMICs due to the vast unavailability of sterility biological indicators and dedicated biomedical staff who are responsible for periodic checks and quality assessments of reprocessed surgical instruments (Forrester et al. 2018).

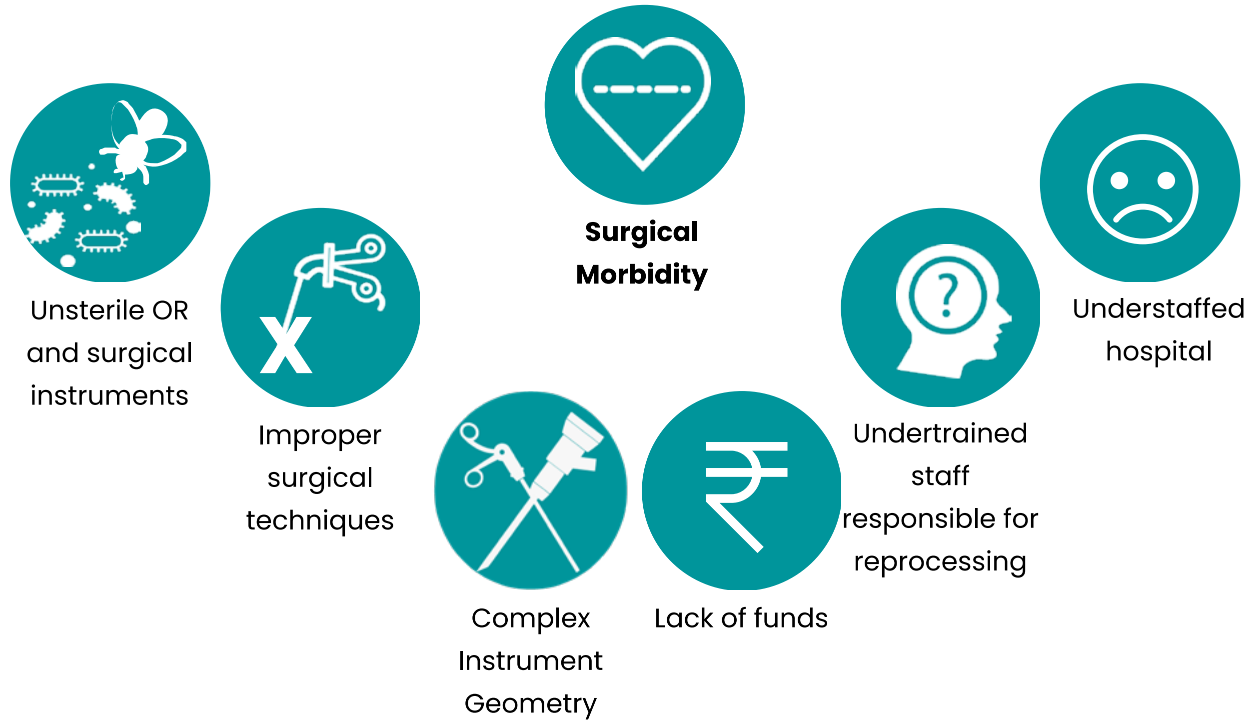


Fig 2.4.1 Overview of reasons for the high surgical morbidity in LMICs

In many HICs, laparoscopic surgeries are conducted using disposable instruments that are affordable due to robust national healthcare systems. However, this is not applicable in LMICs. Rural Indian hospitals themselves are underfunded and often financed through donations by trusts. There are few systems to help alleviate the patient's financial dearth however, disposable surgical instruments and consumables including laparoscopic instruments, are to be paid for by the already financially overburdened patients. Disposable instruments cost one-fourth the cost of reusable laparoscopic instruments, donated to the hospitals by trusts, and are observed to be used 2 to 68 times in order to keep the surgical costs down to meet the financial requirements of rural Indian patients (Jamir et. al 2015).

The shortage of dedicated Central Sterile Supply Departments (CSSD) plays a major role in the inadequacy of sterile surgical instruments. SPDs are special departments dedicated to reprocessing surgical instruments. Unconventional and toxic techniques like cold sterilization, which uses immersing the surgical

“The already vulnerable indigent patients are in exacerbated levels of danger to SSIs due to insertion of these unsterile laparoscopic instruments.”

instruments in glutaraldehyde solution and storage in formalin boxes are used to chemically disinfect surgical instruments. Outdated or lenient training, inadequate supplies, storage, and damaged surgical instruments are a propagating factor for infection spreading (Fast et al. 2017). Improper reprocessing promotes biofilm formation (fig 2.4.2; fig 2.4.3; fig 2.4.4). Biofilms are colonies of pathogens that attach to instrument surfaces and build up a tolerance to enzymatic and antibiotic detergents, rendering the reprocessing useless(fig 2.4.5). Residual moisture and improper sterilization make the complex, long, and slender laparoscopic instruments perfect for biofilm accumulation (Jamir 2015). The already vulnerable indigent patients are in exacerbated levels of danger to SSIs due to the insertion of these unsterile laparoscopic instruments.

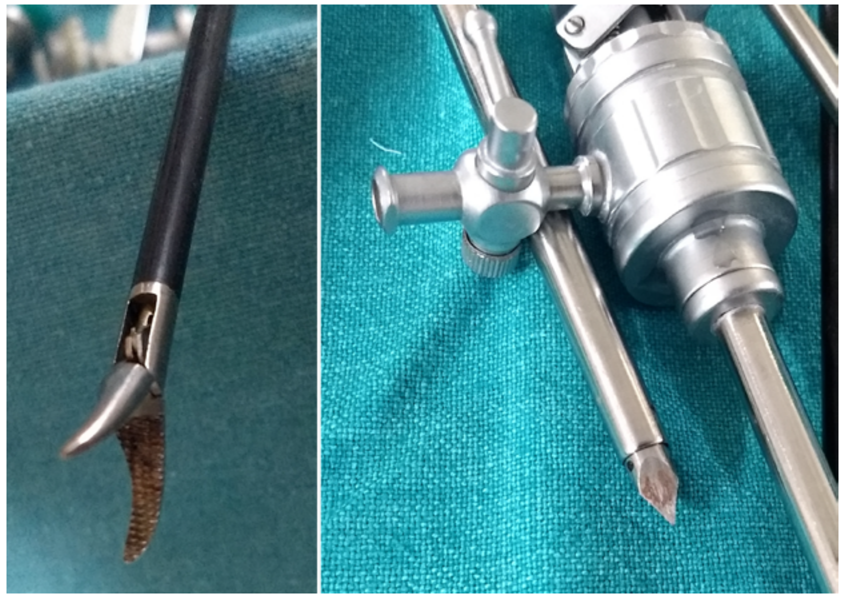


Fig 2.4.2 Traces of bioburden present on the laparoscopic grasper post sterilization (left)
Fig 2.4.3 Traces of bioburden present on the laparoscopic trocar post sterilization (right)

Fig 2.4.4 Traces of bioburden present on the laparoscopic grasper post sterilization.

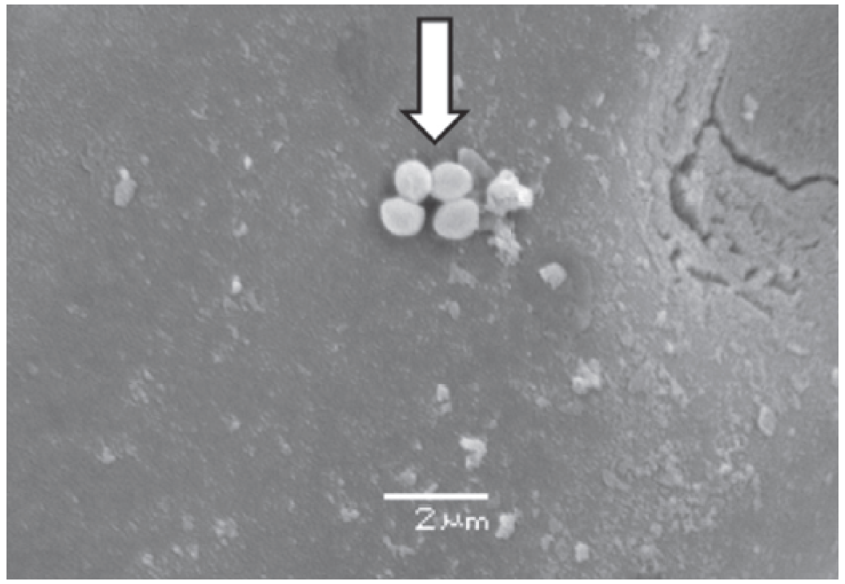


Fig 2.4.5 Surface attached bacteria on a manually cleaned surgical instrument (Lopes et.al, 2018)

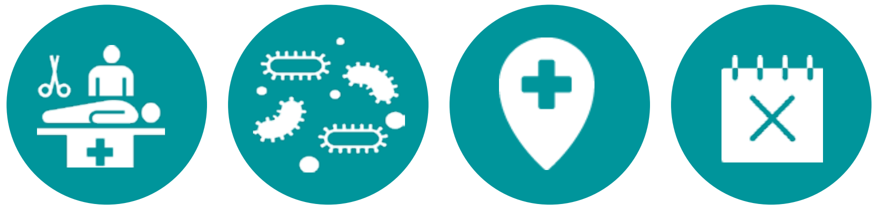
2.5 Risk and Prevention

The prevalence of contracting SSIs is 70% higher among LMIC patients compared to patients in HIC hospitals (Fast et al. 2017). Longer duration of postoperative admittance, resistance to antibiotics, a rise in a financial burden, and a higher chance of mortality (Bardossy et al. 2016) are the risks of suffering from SSIs in LMICs. Prevention is better than cure (Kiernan. 2017). In rural India, SSIs can be prevented simply by proper and strict adherence to sterile processing laparoscopic surgical instruments. However, this is not entirely possible in the already resource-constrained turbulent environment of hospitals in LMICs.

2.6 Impact

The impacts of SSIs are not only financially burdening to the patients of the low-income nations, but also dramatically increase the risk of morbidity and decrease the disability affected life years (DALY) of the patient. Globally, 75% of healthcare-associated deaths are directly attributed to SSI where south and south-east Asia account for the largest DALYS at 48 million (fig 2.6.1) (Ozgediz, D., et al.2008).

In order to make laparoscopic surgery safe and viable in rural India, it is necessary to raise awareness and tackle SSIs by reprocessing the surgical instruments optimally and efficiently.



~313 million surgeries yearly (WHO, 2016)

38% of all HCAIs are SSIs (CDC, 2016)

SSIs increase hospital stay by 3-20 days (WHO, 2016)

48 million DALYs due to SSIs. (Ozgediz, D., et al.2008)

Fig 2.6.1 Impact of Surgical Site Infections.

3 Surgery in Rural India

The aim of this chapter is to give an introduction to the context containing basic information about rural India, the healthcare system and research methods used to fully identify the contextual factors that play a significant role in the implementation of low cost cleaning equipment for laparoscopic surgical instruments.

3 . 1 About India

India is a South Asian country with a significant volume of its landmass in the global hot zone. It is the second most populated nation with a population of 1.3billion citizens. Settlements concentrated in cities make up some of the most densely populated regions. According to the world bank, India is classified as a Low-Middle Income Country with an annual gross national income per capita in the range of $1006-$3955 as per 2016 and is an Official Development Assistance (ODA) Recipient. India is a massive country made up of 28 states and 8 union territories created on linguistic lines in 1956.

India has a total of 19810 rural hospitals (National Health Profile, 2018: p 24). 68% of India's population still resides in rural areas of which 90% of these rural residents are deprived of safe and affordable surgery (Forrester et al. 2018). There is a severe lack of surgical resources in India.

3 . 2 The Indian Healthcare System

The healthcare system pertaining to rural Indian citizens has been created to ease the financial pressure and meet the UN SDGs called Pradhan Mantri Jan Arogya Yojana (PM-JAY). Under this scheme, patients are provided 3 days of hospitalization and 15 day post hospitalization coverage.

The barrier here is that only a fraction of these rural citizens are registered because the rest do not have a bank account, making it impossible for the patients to receive reimbursements. The PM-JAY directly funds the patient's healthcare expenses, however, the patient bears the costs of consumables. There is a lot of pressure on the hospital staff to reuse as much of the equipment as possible to reduce the patient's financial burden.

3 . 3 Surgery in India

As mentioned in chapter 3.1, 90% of India's population lack safe and affordable surgery primarily characterized by a severe shortage in financial, surgical and technical resources. Deficiency in basic infrastructure, unreliable supply chains and incompatibility of existing hardware with the crumbling infrastructure of many rural hospitals play a crucial role in the high rates of morbidity in India (Roy et al. 2019).

Morbidity due to SSI is the most common yet most preventable. Incidences of SSIs in India are estimated to be significantly high at ~38% (Arora et al. 2018) as compared to 10.2% in the Netherlands(McQueen, K et al. 2008). These unbalanced morbidity statistics (fig 3.3.1) can be attributed to unsterile surgical instruments and operation rooms, lack of nursing knowledge, outdated and unorthodox surgical practices in India hence demanding a wide range of measures required to tackle SSI outbreaks (Arora et al. 2018).

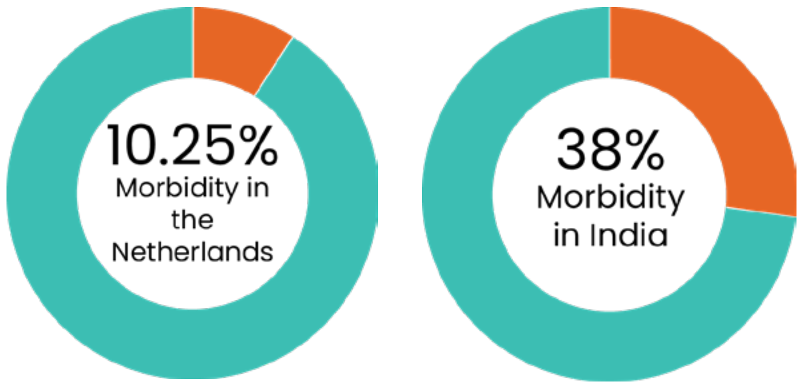


Fig 3.3.1 Impact of Surgical Site Infections.

Guidelines and infrastructure concerning sterile processing in rural Indian hospitals barely exist and none of the facilities comply with WHO Standards. This ignorance of guidelines and hygienic standards makes it challenging to trace the cause of SSIs in rural India as hygienic standards and guidelines are not adhered to.

A vast majority of rural Indian hospitals do not have the means and dedicated facilities to sterilize surgical instruments. Highly recommended stages of the instrument cleaning journey like high-pressure steam autoclaving are substituted by toxic chemical disinfection that shrinks the life of surgical instruments and is detrimental to the patients and nurses.

Even though resources in urban hospitals are far better off than rural hospitals, the mortality rates attributed to unconventional and hostile surgical environments, techniques with the addition of unsterile surgical instruments are in the millions (Arora et al. 2018).

According to an experiment conducted by Vijayaraghavan et al, 145 bacterial portside infection (PSI) outbreaks were found in 35 laparoscopic patients in a period of 6 weeks (Vijayaraghavan et al. 2008). These PSIs were traced to the use of unsterile laparoscopic instruments. The mortality statistics however may be a lot higher, but due to the lack of systems to record and observe mortality statistics, the information for general and laparoscopic surgery is inconclusive.

4 Sterile Processing

Journey mapping is a powerful tool to visualize and gain insights into the different, in this case, chronological phases of surgical instrument reprocessing in high and low-income contexts. Journey maps mentioned in this chapter function as the backbone of the field research and this graduation project.

As quoted by Rene Descartes, "divide each difficulty into as many parts as feasible and necessary to resolve it". Journey maps for HICs and LMICs are created by field observations and interviews. They are then analyzed by breaking them into their fundamental blocks to recognize each step's requirements, processes, and pain points.

4 . 1 Sterile Processing and Reprocessing

One of the key factors in ensuring the quality and safety of healthcare facilities is the reprocessing of reusable surgical instruments. Once reusable surgical instruments come in contact with blood, human tissue, and fluids they become contaminated. Instrument reprocessing involves a combination of specific processes used to render RSIs safe for handling by staff and subsequent use for patients during surgeries. Effective reprocessing of RSIs is an essential component in the prevention of SSIs and HCAIs. Sterile processing is oftentimes an overlooked service in the hospital environment. Using safe and sterile instruments plays the most critical role in patient care (Maurer, S 2012). Decontamination of surgical instruments must be performed before the surgical instruments are used. Failure at any stage may result in inadequate decontamination and unsafe surgical conditions. This section provides a description of the sterile processing cycle and its features as suggested by the WHO Decontamination and Reprocessing of Medical Devices for Healthcare Facilities, 2016 (fig4.1.1).

The WHO decontamination cycle has been divided into 9 stages. Every stage brings the instrument one step closer to ensuring that the surgical instrument is sterile and safe for surgical use. This cycle begins as soon as the surgery is complete till the next surgery that demands the same instruments. Healthcare facilities should ensure to follow this cycle as closely as possible so as to ensure safe surgical instruments and standardized outcomes.

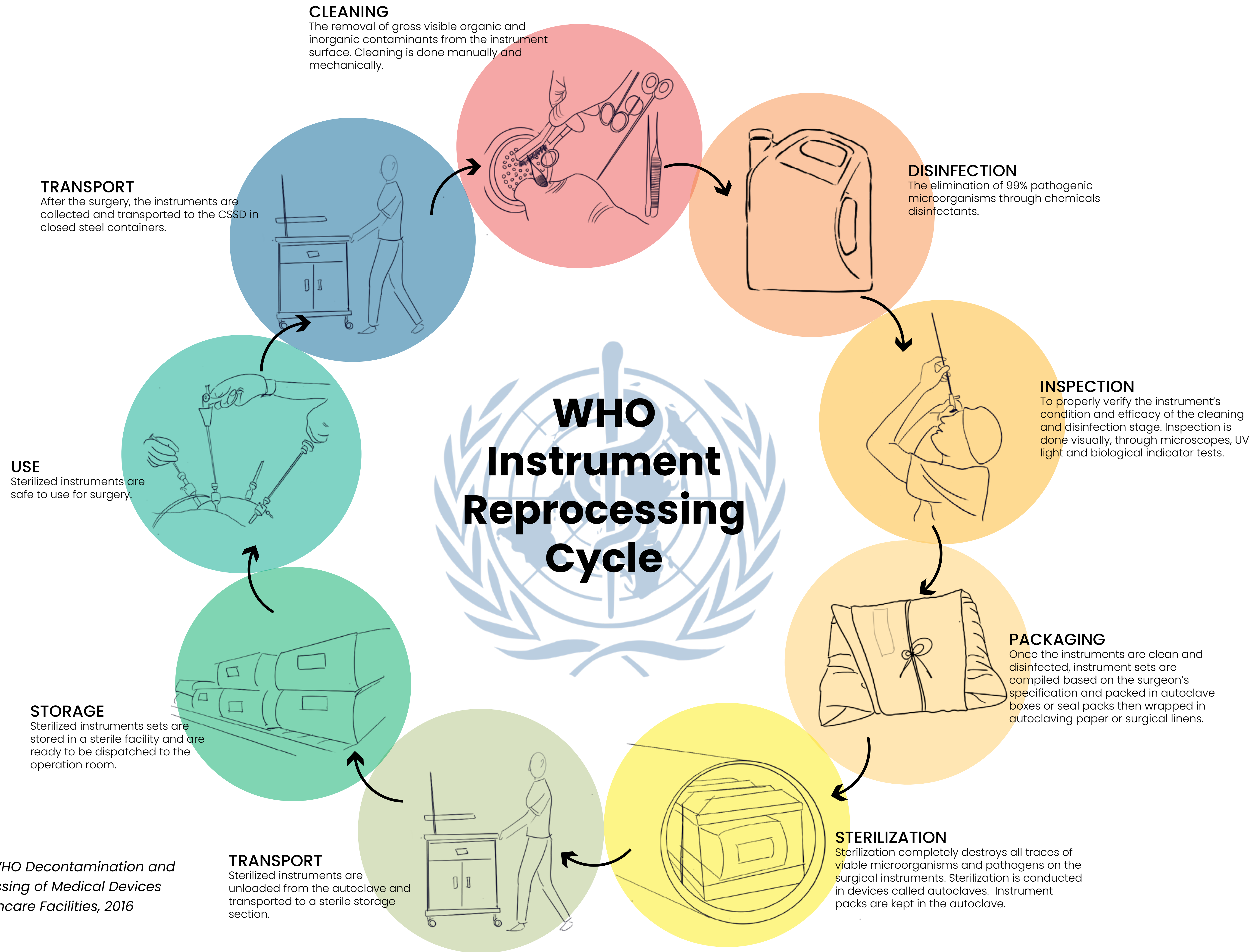


Fig 4.4.1 WHO Decontamination and Reprocessing of Medical Devices for Healthcare Facilities, 2016

4 . 2 Sterile Processing in High Income Hospitals

High-income hospitals in this project, refer to the hospitals that are well equipped in terms of surgical facilities, operating rooms, and CSSD facilities. These hospitals adhere to and operate under strict WHO, CDC, national and local healthcare guidelines and federal policies and could be considered as standard operating procedures for instrument reprocessing. It is important to note that this project field research was affected by the COVID-19 pandemic. Due to this reason, Indian high-income hospitals were not visited and similar hospitals in the Netherlands and the USA were chosen for this study.

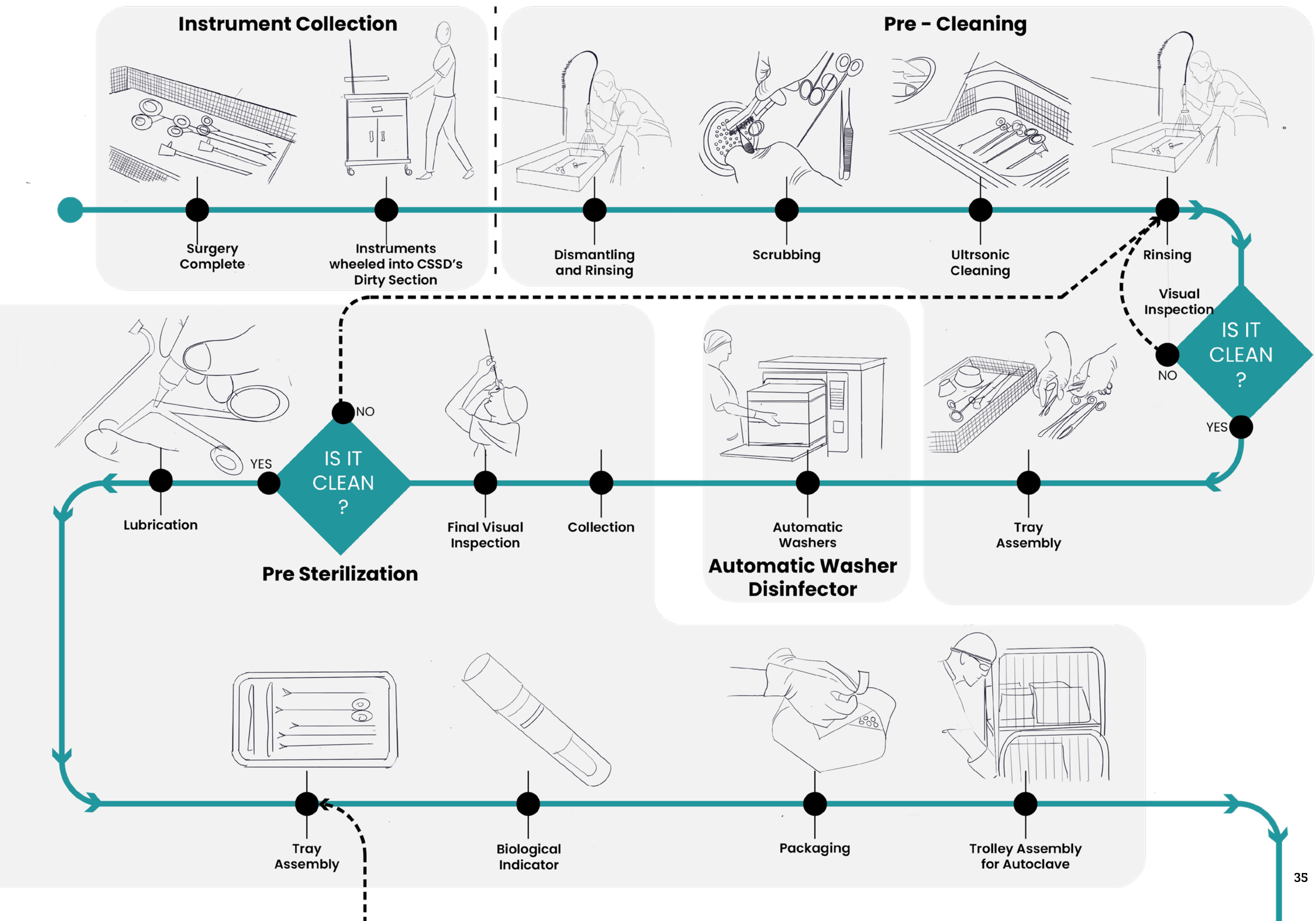
In terms of surgical instrument reprocessing, the high-income hospitals have dedicated CSSDs (fig 4.2.1) with a streamlined procedure for reprocessing a vast number of surgical instruments with minimal user interactions. CSSD staff are specially trained for the task of cleaning, disinfecting, sterilizing, and inspecting surgical instruments.

4.2.1 CSSD in a High Income Hospital

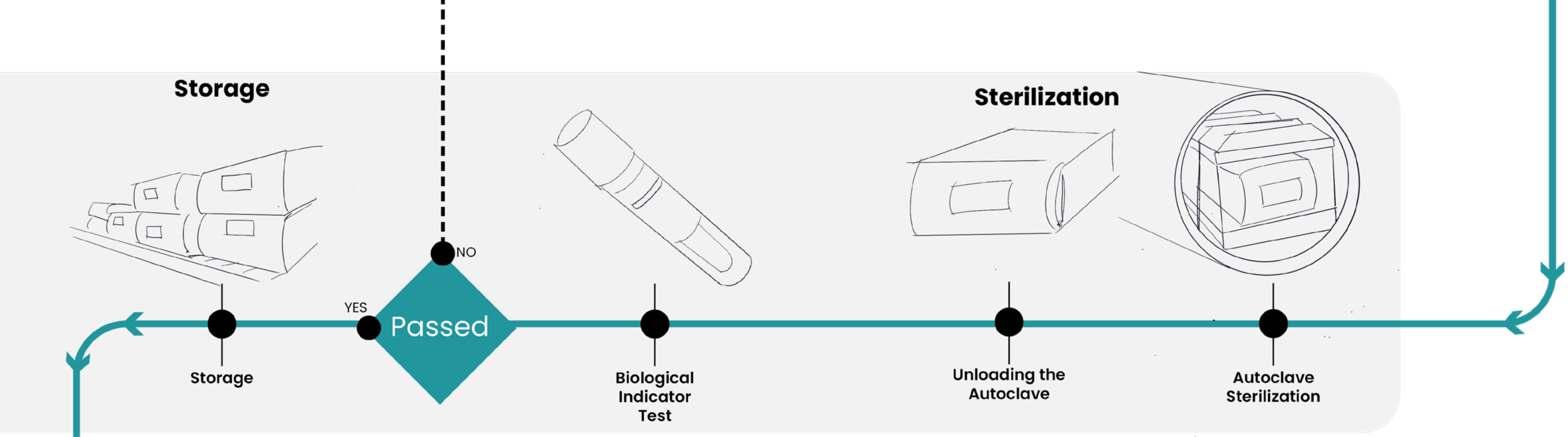
Fig 4.2.1 is an example of a well-supplied and demarcated inspection and packing unit of the CSSD which is considered as a "clean zone" as the instruments are automatically washed and dried pre sterilization.

A field visit to the CSSD of LUMC Leiden, the Netherlands, and a desktop case study of the Southwest Washington Medical Center, USA was conducted to gain a qualitative understanding of the instrument reprocessing journey in the high-income hospitals.

Through these studies, a "High Income Hospital Instrument Reprocessing Journey" is created (Fig. 4.2.2). This methodical approach of researching a context that is the opposite of rural India helped in fragmenting and recognizing the entire reprocessing practice in high-income hospitals into individual steps to learn the procedure, requirements, time taken per step, and pain points. Based on this journey, missing steps in the LMIC hospital cleaning journey are identified. This journey is crucial to understand the key differences between the standard procedure and non-standard reprocessing practices followed in rural India.



Instrument Collection
Pre - Cleaning
Surgery Complete
Instruments wheeled into CSSD's Dirty Section
Dismantling and Rinsing
Scrubbing
Ultrsonic Cleaning
Rinsing
Visual Inspection
IS IT CLEAN ?
NO
YES
Tray Assembly
Automatic Washers
Automatic Washer Disinfector
Collection
Final Visual Inspection
IS IT CLEAN ?
NO
YES
Lubrication
Pre Sterilization
Tray Assembly
Biological Indicator
Packaging
Trolley Assembly for Autoclave



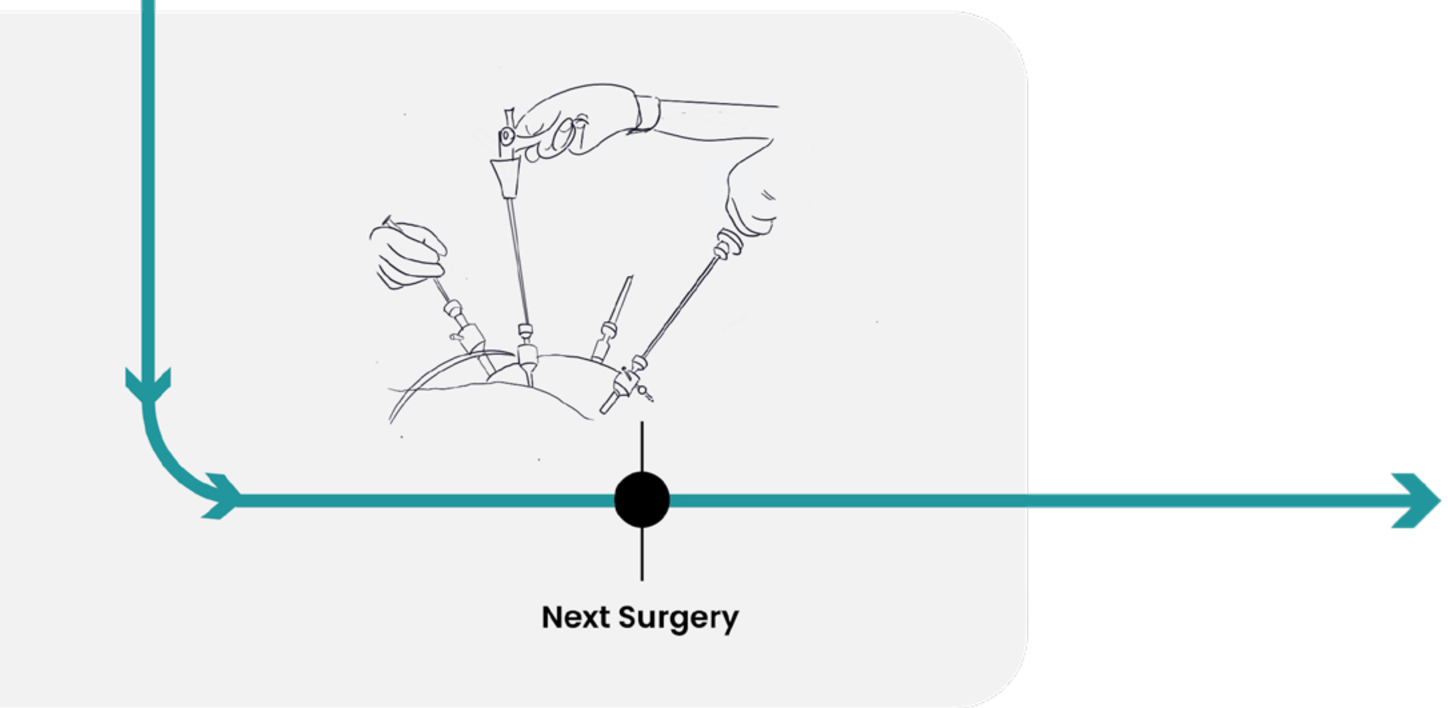


Fig4.2.2 Instrument Reprocessing Journey in a High Income Hospital

In the High Income Hospital Instrument Reprocessing Journey, it is observed that there are six distinct steps with a mix of manual and mechanical interventions.

- Collection (manual)
- Pre Cleaning (manual)
- Cleaning (mechanical)
- Pre Sterilization (manual)
- Sterilization (mechanical)
- Storage (manual)

Key Takeaways

1. There is very little physical interaction of the instruments with CSSD technicians.

2. A clear demarcation is maintained between dirty and clean rooms of HIC CSSD and the instrument journey is linear.

3. Due to strong inspection practices, the surgical tools only go a step backward for a redo.

4. The use of automation is very prevalent in the cleaning and sterilization step.

5. A large volume of instruments can be reprocessed at once due to automation and machine size.

6. High and low temperature sterilizers are used. Hence, all kinds of surgical instruments are sterilized.

7. Toxic chemicals like glutaraldehyde and Formalin are used for sterilization in a safe and contained manner.

8. The entire reprocessing journey is an expensive process because it involves the use of expensive machines, high volumes of water, detergent, well trained and paid dedicated sterile processing technicians and use of disposable indicators.

9. The time taken for reprocessing each batch of surgical instruments from acquisition into CSSD to sterile storage is 4 hours.

10. High income hospitals maintain a massive inventory of extra instrument sets that prevent the need for fast and uninspected instruments from reaching the surgeon's tray in times of surgery.

4 . 3 Sterile Processing Rural India

As discussed earlier, the practice of reprocessing laparoscopic instruments in rural India has been unable to keep up with the pace of development of advanced laparoscopic instruments capable of performing complex procedures. In order to fill this void and avert failure of newly developed systems and products, an in-depth analysis of the contextual barriers has been conducted. This chapter is dedicated to the exploration of sterile processing practices in rural Indian hospitals. Data has been collected through field visits and interviews.

4 . 3 . 1 Rural Indian Hospital Environment

A thorough analysis of field visits conducted ir. Daniel Robertson to Indian hospitals in 2020 was conducted by visiting 4 hospitals in widely dissimilar rural Indian geographical contexts (fig 4.3.1) to observe and validate assumptions of sterile processing practices. Appendix A gives a detailed description of the existing sterile processing infrastructure, current practices, and resources available. Findings and insights into this field visit will form the base of this project.

This chapter focuses on the observed commonalities of the conditions in the 4 hospitals, casting a focus on the conditions of the operation rooms, nurse safety, disposable instrument reusing practices, and sterile processing facilities (appendix A).

Hospital administration of these rural hospitals declined the request to use their names and are hence called Hospital A, B, C, D for the entire duration of this report.

Interviews with rural Indian surgeons and nurses were conducted in order to get first-hand perspectives about surgical conditions and practices. Through the data collected from these field observations, an "Existing Laparoscopic Surgical Reprocessing Journey in Rural Indian Hospitals" is created and discussed in detail in chapter 4.4. This journey map is created to observe the non-standard reprocessing practices of rural India.

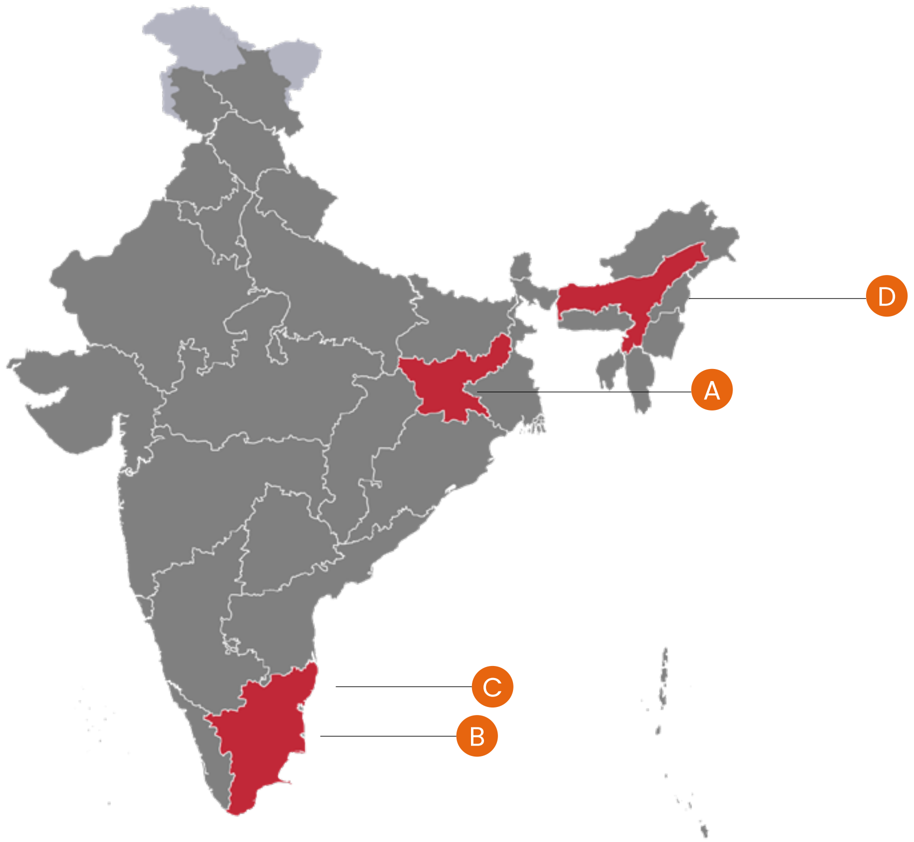


Fig 4.3.1 Locations of the four hospitals in India.
A: Jharkhand; B, C: Tamil Nadu; D: Assam

i) Unsterile Operation Rooms

Through field observations, it was observed that the condition of the operating rooms of these hospitals is indeed unsterile and at times chaotic (fig4.3.1 - fig4.3.5). Having completely sterile operating rooms is a highly important factor for ensuring safe surgery and reduction of surgical site infections but due to lack of financial and technical support, rural surgeons are at times forced to frugally improvise with existing resources to get the job done. This was observed in all the hospitals. Fig 4.3.2 and fig 4.3.3 illustrate the operation rooms in hospitals A and B. It can be observed that hospital B's OR is severely underdeveloped and lacks the basic amenities for laparoscopic surgeries.

Fig 4.3.2 Hospital A, Jharkhand

Fig 4.3.3 Hospital B, Tamil Nadu

Fig 4.3.4 Hospital C, Tamil Nadu

Fig 4.3.5 Hospital D, Assam

ii) Lack of Personal Protective Equipment

Personal Protective Equipment (PPE) is the protective garments worn by nurses while cleaning surgical instruments to prevent transmission of HCAIs to nurses. Rural Indian nurses are not equipped with standard PPE (fig 4.3.7) and are constantly exposed to aerosolized water from scrubbing, fumes from glutaraldehyde and formalin and in danger of getting injured by sharp surgical instruments. The lack of protection from the above factors put hospital staff and nurses in great danger of contracting HCAIs.

iii) Reuse of Disposables

Cost awareness in rural India is up to a level where any disposable that can be reused will be reused. The underfunded hospitals have an obligation of keeping healthcare costs low for their patients. According to the healthcare system, the patients have to pay for disposables and medicines to keep the surgical costs to a minimum. 40% of rural Indians either borrow large amounts of money or sell property to make funds for treatment (Jamir et al. 2015). It is hence very necessary to ensure reusable surgical instruments are safe and sterile for use.

iv) Lack of Sterile Processing Department

Unsterile reusable surgical instruments pose a major risk in spreading infections in already vulnerable patients. The CSSD is dedicated to reprocessing used surgical and medical instruments and is a prominent aspect of curbing the spread of SSIs (Southworth, 2016). Rural Indian hospitals visited did not have dedicated CSSDs. It was observed that nurses and surgeons used the same sinks to wash soiled instruments and scrub before surgery respectively(fig 4.3.6- fig 4.3.9).

These sinks were adjacent to the operating rooms as seen in fig 4.3.8, exacerbating the risk of cross contamination an important factor for unsterile ORs. Some laparoscopic instruments are coated with insulating plastic sheath, rendering them incapable of conventional autoclaving. Most hospitals did not have functional autoclaves and washer disinfectors either.

Fig 4.3.6 Instrument reprocessing platform in Hospital A (top) —There is a clear lack in devices required to help the nurse with the cleaning. The washing and drying areas are very close to each other. Washing dirty instruments beside washed instruments kept to dry could cause cross contamination.

Fig 4.3.7 Nurse is scrubbing surgical instruments in a sink in Hospital B (left)—The nurse is not protected with proper PPE. He is cleaning the instruments atop kitchen sink without a mask, apron or body suit.

Fig 4.3.8 Instrument reprocessing regions in Hospital C (top) —The sink for scrubbing and cleaning instruments is very close to the OR. This highly excerbates the risk for contamination of the OR.

Fig 4.3.9 Laparoscopic and general surgical instruments accumulated together after manual scrubbing in hospital D (right)

4.3.2 Exploring the Instrument Reprocessing Journey in rural India

The field visits and interviews have furnished holistic insights into how instruments are reprocessed in rural India. In order to improve the reprocessing of laparoscopic surgical instruments in LMICS, a complete in-depth study of the current practices of reprocessing surgical equipment is conducted.

During the field visit, surgical trays were inspected to get an idea of the different kinds of laparoscopic instruments used in the operation room. Fig 4.4.1 illustrates a clear example of a standard laparoscopic instrument tray in rural Indian hospitals. The image is used for counting instruments used in the surgery.

Fig 4.4.1 Instrument tray for a laparoscopic surgery in Hospital D

The above image of the instrument tray clearly shows 3-4 graspers and trocars, 2 laparoscopes, 2 irrigation/suction lumens, and miscellaneous surgical scissors, forceps, and retractors. The laparoscopic instruments commonly used are 5mm and 10mm graspers with coinciding trocars. The surgical Instrument count gives an example of what instruments are used, their quantity, and sizes. This gives a clear idea of the design requirements for developing a frugal laparoscopic instrument reprocessing system for rural Indian hospitals.

The field visits disclosed that adherence to national and international guidelines for reprocessing is absent and there are no observed standardized reprocessing practices either. This chapter is dedicated to a detailed journey map of the entire existing reprocessing journey of surgical instruments between subsequent surgeries in rural India to help visualize the existing practices, systematically and methodically describe every step of the process with details and identification of pain points (fig 4.4.2).

An interview with a nurse in rural India disclosed that the surgical instruments used in rural India after reprocessing are only 70% clean and safe. In terms of surgical safety, this number is very concerning.

An instrument checklist (appendix A) made by ir. Daniel Robertson on his 2020 field visit clearly portrays the equipment available in the four rural Indian hospitals. The existing reprocessing journey in rural Indian hospitals can be broken down into four distinct steps.

Collection of Instruments

Manual Cleaning

Disinfection

Storage

"the surgical instruments used in rural India after reprocessing are only 70% clean and safe"

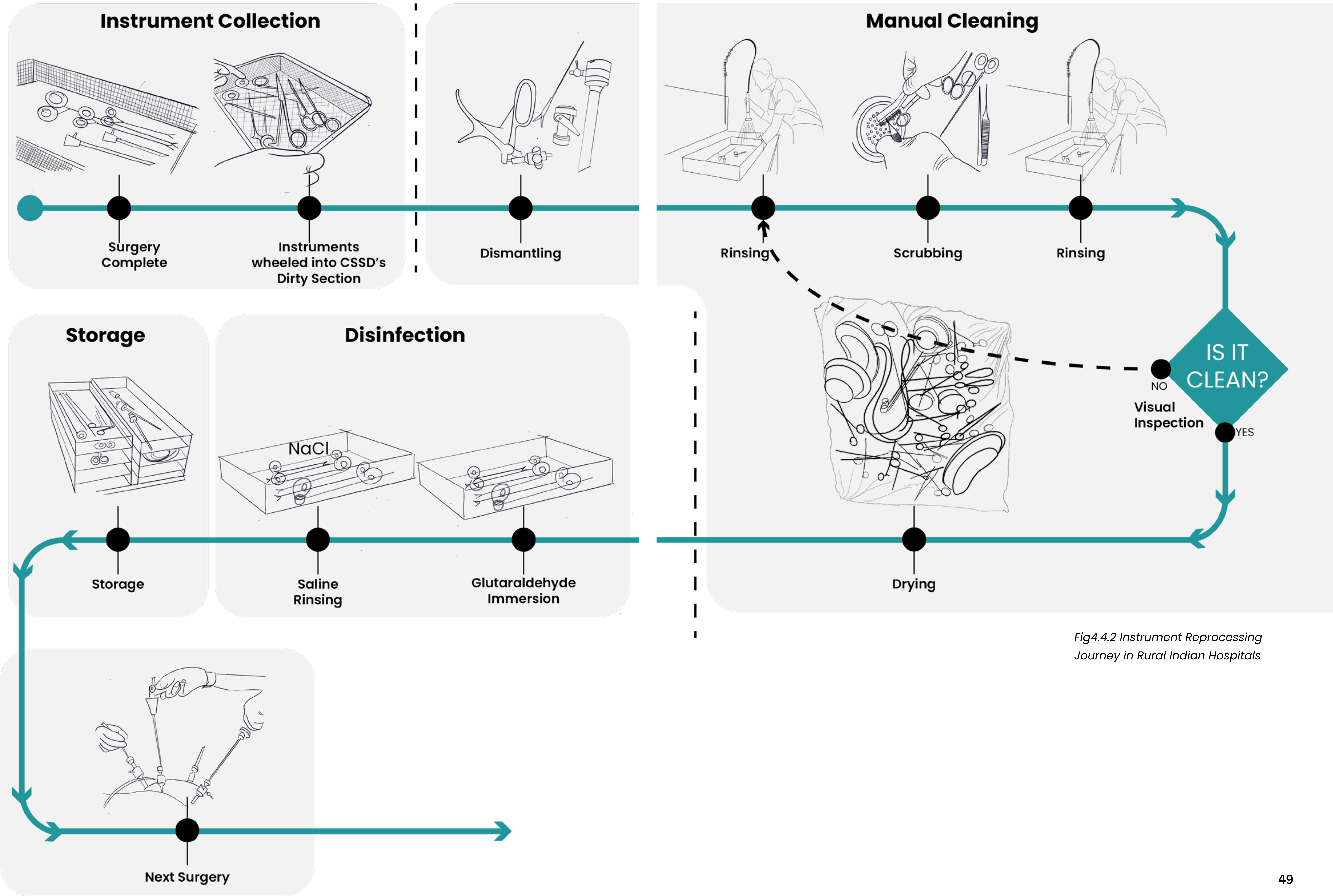


Fig4.4.2 Instrument Reprocessing Journey in Rural Indian Hospitals

1. **Instrument Collection**

Used surgical instruments soiled with blood, proteinaceous deposits and other miscellaneous bioburden are collected in a steel tray by the nurse after a laparoscopic surgery. Used surgical instruments are at times kept in dry surgical trays where blood and other fluids dry and adhere to the instruments, reacting and corroding the instrument material.

Pain Points

- Dried blood is difficult to scrub by nurses.
- Cleaning areas are far from the OR.

2. **Manual Cleaning**

The process of manual cleaning of surgical instruments is divided into 6 steps dismantling; rinsing; scrubbing; rinsing; visual inspection; drying.

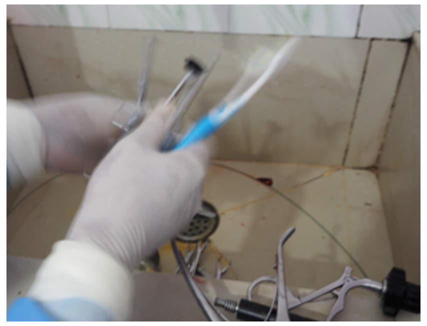


Fig 4.4.3 Instruments being rinsed in a sink which was in close proximity to the OR.

i) Rinsing 1

Soiled surgical instruments are removed from the instrument trays and dismantled by the sink and rinsed with clean running water. Rinsing is done in sinks where most surgical instruments are washed by hand, similar to rinsing utensils. Old toothbrushes and syringe needles to scrape and pick out stubborn bioburden. (fig 2.4.3)

Complex and slender devices like laparoscopic instruments are even more challenging for nurses to rinse out as bioburden collects in hard to reach spots and cannot be washed away under a tap.

Pain Points

- RInsing sinks in close proximity to the OR exacerbate the risk of contamination spread. These sinks are also used for surgeons to scrub themselves before surgery.
- Nurses are not equipped with proper PPE and are unprotected from splashing, aerosolization and blood borne pathogens like HIV and hepatitis.
- Hollow laparoscopic instruments take longer to rinse.
- Nurses may not know the patient's health condition. Contact with patient's residual fluids on the soiled instruments is dangerous.

ii) Scrubbing

Blood and bioburden is scrubbed off the surgical instruments using friction with the help of toothbrushes, needles, sponges, bleach and detergent powder (fig 2.2.4; fig 2.2.5). It was observed that nurses spent extra time while scrubbing hollow laparoscopic instruments like graspers and trocars due to their inherent complexity and scarcity of the correct cleaning tools.

Pain Points

- Instruments are scrubbed with detergent powder and bleach powder Both are corrosive and detrimental to the instrument and nurse's health.
- The buildup of calcified deposits inactivate disinfectants, cause allergic reactions and release endotoxins in the patient
- Bleach and detergent powder may not be enzymatic. Enzymes may still be present on the instrument.
- Nurses are not provided with proper tools to scrub the instruments.
- Laparoscopic instruments take longer to scrub.
- Nurse is not equipped with PPE.

Fig 4.4.4 Contaminants being chipped out of the grasper teeth with an old syringe needle.

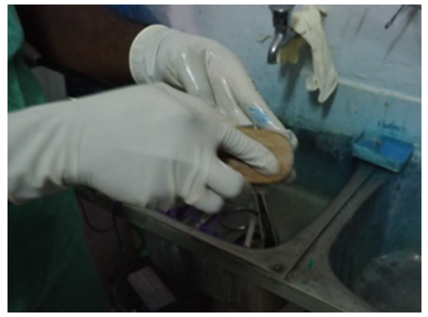


Fig 4.4.5 Surgical instruments being scrubbed with a sponge.

iii) Rinsing 2

Chemical agents, detergents and loose bioburden are rinsed off the instrument under running water. It is established that the absence of the correct cleaning tools and enzymatic detergents do not effectively eliminate bioburden and chemical residue. After scrubbing laparoscopic instruments, rinsing out residual particles has been observed to be a great hassle due to the general nature of the instrument and hollow instruments take significantly longer to rinse.

Pain Points

- Bioburden and clumped powder residue could still be present on the instrument.
- Laparoscopic instruments take longer to rinse.

iv) Visual Inspection

Nurses in rural India are trained in general nursing and midwifery and do not have specific training in sterile processing, detecting and recognizing pathogens, thus reducing the efficacy of visual inspection. Accountability is hindered in this context because the practice of logging in steps by responsible nurses are absent. Hence, visual inspection of the scrubbed and rinsed laparoscopic instruments are inadequate.

Pain Points

- Inspection is done visually. No Microscopes and culture tests are performed to test the instruments cleanliness.
- Microscopes bioburden is not detected.
- Nurses are not trained to detect and identify pathogenic substances and do not know what to look for.
- Hollow and laparoscopic instruments are difficult to visually inspect for dirt.

v) Drying

Laparoscopic instruments are dried in the open (fig 4.4.6) or with hair dryers but take a longer time to dry as water collects in trocar shafts and grasper as residual water droplets harbour pyrogenic toxins, bioburden and detergent residue. The complexity of the instruments reduces the speed of the drying process. The instances of laparoscopic surgery in India has considerably risen, thus demanding faster reprocessing because rural hospitals cannot afford a large inventory of these expensive instruments. The semi-dried, semi-cleaned laparoscopic instruments are taken to the next stage without quality assessment practices.

Pain Points

- Drying takes a lot of time.
- Water when dried on the surface leaves residue which may be contaminated with chemicals and pathogens.
- Hollow and laparoscopic instruments may not dry easily or take a long time to dry.
- Pockets of residual water collect in the hollow parts of the instrument.

Fig 4.4.6 Surgical instruments are left on the floor to dry after manual cleaning.

Fig 4.4.7 Surgical instruments immersed in 2% glutaraldehyde solution.

3) Disinfection

Disinfection is the process of chemically eliminating pathogens. The disinfection steps observed in rural india consist of glutaraldehyde immersion and saline rinsing.

i) Glutaraldehyde Immersion

Glutaraldehyde Immersion consists of using 2% activated glutaraldehyde solution, commonly referred to as CIDEX. Assembled instruments are immersed in a soaking tray of this green solution(fig 4.4.7). Instruments are immersed in glutaraldehyde solution for 12-20 minutes. This is the most common and widely applied process of disinfection. This step, even though a crucial factor in the reprocessing of laparoscopic instruments has been observed to have demerits, rendering the instruments used dangerous for subsequent surgeries.

Pain Points

- Strict vigilance of the soaking time is not maintained.
- Glutaraldehyde is toxic irritant to the skin, eyes and respiratory tract, adding to the health risks of the already vulnerable nurses performing sterile processing without proper PPE.
- Partially dried laparoscopic instruments leach residual water and contaminants into the glutaraldehyde bath, reducing it’s concentration and efficacy
- Assembling complex instruments prior to immersion restricts complete penetration of the solution in the instrument, leaving certain areas of the instrument unserile
- In many cases,only the tips of disposable plastic graspers are immersed in glutaraldehyde solution, leaving the rest of the grasper to be cleaned with isopropyl alcohol. Biofilm on surgical instruments and cleaning tools are resistant to inactivation by chemicals.
- Immersion trays were observed to have a layer of biofilm which are a major yet unchecked factor of spreading SSIs.

ii)Saline Rinsing

Glutaraldehyde solution is rinsed off the disinfected surgical instrument by immersing them in saline water. Instruments are simply transferred from the disinfection to the rinsing tray to wash away the glutaraldehyde solution. The saline water fails to fully percolate into the assembled instrument, preventing the glutaraldehyde solution from rinsing away. A nurse interview stated that the saline water is not replaced often, thus contaminating the disinfected laparoscopic instruments. Biofilm accumulation is common in the saline trays, propagating the risk of SSIs.

Pain Points

- Saline water is not replaced often and is often contaminated.
- Saline trays may accumulate biofilm and suspended particles.
- Saline water does not fully percolate into every part of the instrument. Glutaraldehyde solution may still be present after saline rinsing.

Fig 4.4.8 Formalin tablets for storing disinfected instruments.

Fig 4.4.10 Non Laparoscopic instruments stored in closets.

Fig 4.4.9 Laparoscopic instruments stored in plastic boxes with formalin tablets.

4) Storage

Storage is the final step of the instrument reprocessing journey. It is of absolute importance that the instruments are wrapped in surgical linen and stored in a sterile facility or in a sterile manner.

Rural Indian hospitals did not have sterile storage facilities and laparoscopic instruments are not stored in autoclaved linen. Miscellaneous instruments are stored in closets that do not guarantee sterility (fig 4.4.9) The growing demand for laparoscopic surgery prevents nurses from storing the instruments but disinfect them in glutaraldehyde solution, rinse in saline water and perform the next surgery.

However, instruments are stored with formalin tablets (fig 4.4.8) till the next laparoscopic surgery is scheduled. Formalin releases formaldehyde gas, even though gentle on the instruments, it is highly toxic for nurses and hospital staff, causing skin, eye and respiratory tract irritation on long term exposure.

Pain Points

- Sterile storage is not available.
- Hollow and laparoscopic instruments may not be fully dried after disinfection.
- Formalin is a toxic irritant to hospital staff.

4 . 4 Comparison between HIC and rural Indian Hospital Instrument Reprocessing Journey

In the previous chapters, a deep analysis of surgical instrument reprocessing journeys in high-income hospitals like LUMC Leiden and four rural Indian low-income hospitals is conducted. It can be established that the high-income hospitals adhere to the recommended WHO standard operating procedure, hence the ideal reprocessing journey. Through field observations and interviews, the description, pain points, and requirements of every step of both the journeys have been detailed.

In this chapter, both instrument reprocessing journeys have been compared by placing them parallelly (fig 4.5.1). The aim of this comparative analysis is to recognize the voids in the rural Indian instrument reprocessing journey (LMIC) compared to the high-income hospital cleaning journey. These voids are recognized as potential design directions.

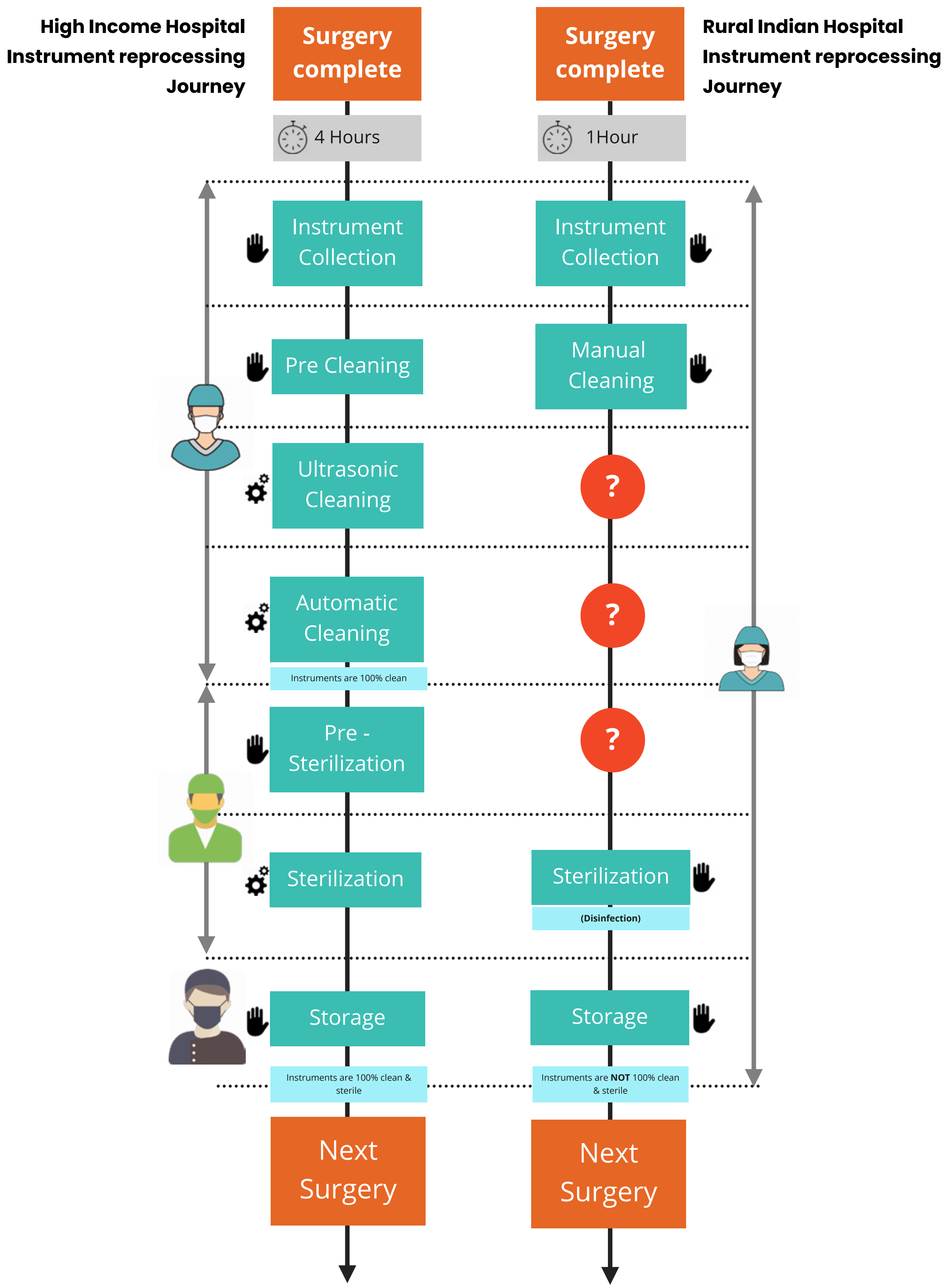


Fig 4.5.1 Comparitive study between HIC and Rural Indian hospital instrument reprocessing journey.

The differences between LUMC Leiden and rural Indian hospitals are extensive. Major steps are seen to be absent in the rural Indian reprocessing journey. The comparative study has revealed that HIC hospitals seldom interact directly with the soiled instruments. The strict inspection and safety protocols, a large inventory of instruments and a strict demarcation between dirty and clean zones in the CSSD in HIC hospitals make them effective in guaranteeing sterile surgical instruments, which is not the case in rural India.

Rural Indian hospitals cannot afford to own multiple sets of instruments. Even two sets of laparoscopic instruments deems the rural hospital "well supplied" (interview). Due to the disproportion of less instrument sets and a high number of surgeries schedules (sometimes in close succession on the same day), rural Indian nurses are compelled to superficially clean the instruments, disinfect and use in the next surgery. The total time taken to reprocess surgical instruments in rural India is only one hour, compared to four hours in HIC hospitals.

The comparative study reveals a clear absence of mechanical cleaning in rural India. Mechanical cleaning involves using mechanical systems like ultrasonic cleaners and washer-disinfectors to clean the instrument from surgical debris on the laparoscopic instruments. This is a highly critical step because mechanical interventions limit the nurse's interactions with soiled pathogenic surgical instruments thus preserving and maintaining a certain degree of safety and standardization of outcome.

The already overburdened nurses in rural India are responsible for ensuring clean and sterile surgical instruments. A severe lack in time, proper cleaning tools, safety, PPE and inspection training adversely affect the quality of reprocessed instruments. Fig 4.5.2 illustrates the key points in the comparative study between the instrument reprocessing journeys of both contexts.

The table in the subsequent page illustrates the sumary of the differences between hich income hospitals and rural Indian hospitals.

High Income Hospital	Rural Indian Hospital
Little physical interaction with soiled surgical instruments.	Lots of physical interaction with soiled surgical instruments.
Strong demarcation between dirty and clean zones in the CSSD.	Demarcation between dirty and clean zones in the sterile processing area is almost absent.
Strict inspection protocols are followed using visual and biological indicators.	Little to no inspection is done. Biological indicators are only used in some autoclaves.
Large quantities of instruments are reprocessed simultaneously.	Very small quantities of instruments are reprocessed simultaneously.
The CSSD supports reprocessing of all types of instruments.	The sterile processing area does not support a wide variety of instruments to reprocess.
Large instrument inventory is maintained.	Rural Indian hospitals have a very small instrument inventory.
Multiple trained sterile processing technicians are involved in every step of the journey	All instrument reprocessing is done by a small group of nurses and at times, a single nurse.
Sterile processing is expensive.	Sterile processing cheaply done.
Sterile processing technician's safety is of high priority.	Nurse's safety is not a high priority.
100% Sterility is guaranteed.	100% Sterility cannot be guaranteed.
Each batch takes ~4 hours to reprocess.	Each batch takes ~1 hour to reprocess.

4 . 5 Sterile Processing Workforce

It is necessary to take a step back and analyze the human resources required to take on the crucial task of sterile processing. Through field research and observations in the Dutch and rural Indian hospitals, stark differences between the workforces in both contexts were observed. This section is dedicated to the understanding of the hospital staff incharge of reprocessing in both contexts.

High income hospitals, in this case LUMC Leiden, employ dedicated sterile processing technicians (SPT). SPTs are the foundation of the hospital's surgery unit by making sure the surgical instruments are safe to use and mitigate the spread of HCAIs. As mentioned in chapter 4.5, the SPT in HI hospitals are highly educated and trained under dedicated sterile processing programmes and well supplied with PPE and devices to aid in proper instrument reprocessing. Owing to the high budget and a large workforce, CSSDs can guarantee the supply of safe and sterile surgical instruments with a high degree of certainty making the job of ans SPT a highly paying and high risk job.

The same is not the case in rural India. These hospitals operate on donations and trusts, hence lack the funds to employ dedicated SPTs. Among a plethora of other important duties (4.6.1), nurses are the primary staff responsible for sterile processing deeming them the backbone of the healthcare system (Khomami et al. 2019).

Education systems for nurses in rural India are greatly inconsistent due to outdated training methods. Nurses come from financially deficient backgrounds, read and write local languages and work as nurses to make ends meet and provide for their families. The incentives of building a career is lacking (interview). It was mentioned that the nurses were only given general training and not specially trained for cleaning laparoscopic instruments and are not treated any differently from conventional instruments.

Nurses are devoid of basic PPE and all manual cleaning is done with regular household items like toothbrushes, sponge, steel wool then dried by hair dryers (Jesudian et al 2015).

Automation, inspection and quality assessment were observed to be lacking in the four hospitals of the field visit. Nurses are not trained to perform routine pathological tests and unaware of the repercussions of unclean common and laparoscopic surgical instruments.

In summary, rural Indian nurses are highly overworked and stressed, single handedly doing the job of a well supplied sterile processing team (fig 4.6.2).

Due to all the factors mentioned in the above section, rural Indian nurses are considered as the primary stakeholders (appendix B) and target group for this graduation project. The design directions taken in the subsequent chapters will focus on the nurse's requirements.

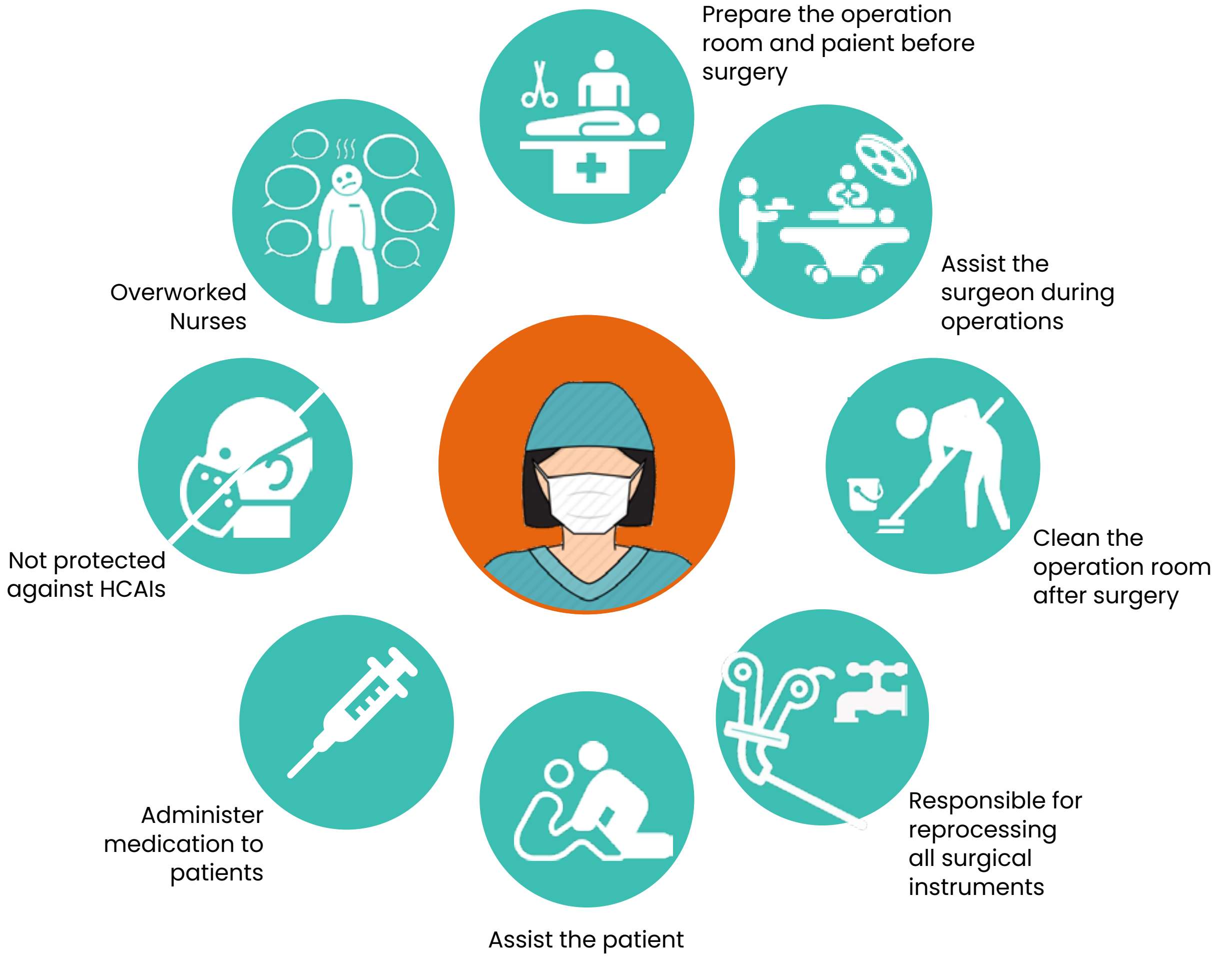


Fig 4.6.1 Rural Indian Nurse as the primary target group.

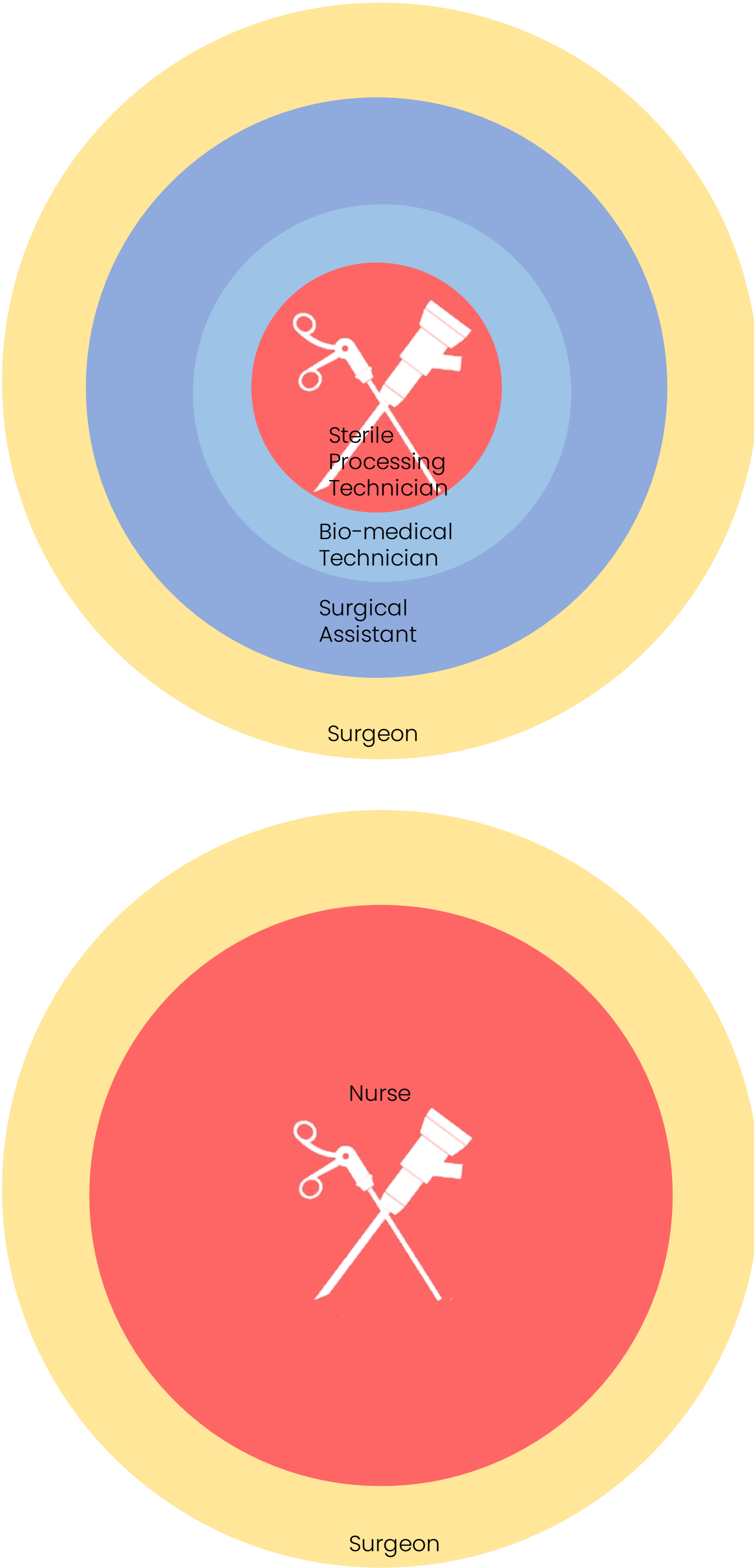


Fig 4.6.2 Hospital staff involved in sterile processing in high income hospitals (top); rural Indian hospitals (bottom).

4 . 6 Conclusion

The discovery phase of the project has been that of deep and insightful understanding of laparoscopic surgeries, instruments and analytical exploration of the sterile processing practices followed in high-income hospitals like the ones in the Netherlands and rural India. Field visits and interviews conducted have been crucial in validating assumptions in addition to getting a first-person perspective of how sterile processing actually takes place in these vastly different contexts. Voids in the rural Indian practices are prominently visible when both contextual journey maps are laid out parallelly.

From the lack of finances, untrained hospital staff, and severe resource constraints, the rural Indian reprocessing practices are vastly rudimentary and far from the WHO's suggested guidelines. It is clear that the sterile processing practices implemented in HICs are absolutely unfeasible for LMICs. Frugal innovations better suited to the rural Indian contexts are necessary to promote safe surgical practices and reduce occurrences of SSIs. Therefore, considering the rise in demand for laparoscopy in rural India, the need for quick yet effective methods of reprocessing these instruments is being addressed in this project.

Several recurring observations were made during this phase. Nurses being the primary workforce of the rural hospitals were observed to be overburdened and unable to efficiently clean the instruments. Lack of mechanical interventions and PPE exposed them to the threat of injury and infections due to handling instruments. Their inability to dedicate undivided attention to reprocessing, fluctuating methods of inspection, and verification between hospitals, and a general absence of dedicated CSSDs together contribute to unsterile surgical instruments. Suitable interventions in rural Indian hospitals are hence necessary to promise similar degrees of instrument sterility with consistent outcomes to curb perioperative morbidity and alleviate the nurse's workload.

The next step to the project is to identify and define the most important problems to be tackled and create a pathway for further development of the project.

5 Define

Opposite to the Discover phase that demands a divergent outlook to amass information regarding sterile processing and a contextual overview, the Define phase requires convergence to the most important and feasible issues relevant to the scope of the project to pave a path to the desired outcome.

A plethora of problems have already been identified in the rural Indian reprocessing practices in the previous phase. Some of these problems can be tackled easily through cost effective methods whereas others require very expensive and extensive interventions. This phase is dedicated to identify those problems which are most feasible to be tackled by design and to eventually formulate the problem statement for this project.

5 . 1 Scoping the Problems

" ultrasonic cleaning does not necessarily demand a design intervention and the scope of this project can be shifted to mechanical cleaning."

As mentioned in section 4.4, the high-income journey could be considered as a standard operating procedure for instrument reprocessing as these CSSDS are built, designed, and operate under strict local and international healthcare guidelines as compared to rural Indian practices. Out of many pressing concerns like nurse safety, training, and lack of CSSDs, the absence of mechanical interventions for reprocessing seemed to be the most prominent. Interviews revealed that the nurses do all the work by hand because they are either not trained to operate cleaning devices due to outdated training programs, the hospital cannot afford to purchase and operate these devices or nurses have never been exposed to the idea of dedicated devices to support their reprocessing duties.

A tier 2 hospital surgeon in Mumbai stated that even though ultrasonic cleaners are extremely cheap, simple to use, maintain, and are highly efficient devices, there is no real reason why ultrasonic cleaners are absent in most hospitals. The hospitals might not have purchased one or the nurses were never exposed to the idea of such a device.

It is safe to assume that the implementation of ultrasonic cleaning does not necessarily demand a design intervention and the scope of this project can be shifted to mechanical cleaning.

5 . 2 Why Mechanical Cleaning?

Cleaning is the gross removal of visible organic (bioburden), inorganic material from the surgical instruments surface manually with the help of water, mechanically with the help of ultrasonic cleaners and automated washer-disinfectors (fig 5.2.1).

To achieve high level disinfection and sterilization, thorough cleaning is the most important and is also the first step. Residual contaminants on the instrument surfaces could reduce the efficacy of detergents and promote biofilm formation (Lopes et.al 2019). If the biofilm is left unchecked, it could bake into the instrument surface, rendering the sterilization process useless(interview)Hence, there can be cleaning with sterilization but never sterilization without cleaning.

"there can be cleaning with sterilization but never sterilization without cleaning"

MANUAL CLEANING	MECHANICAL CLEANING
1. Involves scrubbing, washing and rinsing	1. Involves use of ultrasonic cleaners and washer-disinfectors to clean instruments
2. Requires dedicated time and human intervention	2. Does not demand dedicated human resources and intervention
3. Unsafe. Manual cleaning exposes nurse to harmful pathogens	3. Safer. Mechanical cleaning reduces the exposure of nurse to harmful pathogens
4. Does not guarantee standardized outcomes	4. Guarantee standardized outcomes
5. Nurses are more liable	5. Nurses are less liable

Fig 5.2.1 Cleaning methods for surgical instruments.

" Automated cleaning methods are highly recommended because they are more likely than manual methods to be reproducible and they can be validated."

-Evangelista.S et al (2015)

Laparoscopic instruments pose high degrees of inaccessibility during cleaning. Intricate regions of laparoscopic instruments are inaccessible by brushes, sponges and detergents and they only eliminate a small percentage of the bioburden (Hariharan et.al 2018). Instruments are sharp and complex, putting the PPE devoid nurses in harm's way during instrument reprocessing making manual cleaning in rural India dangerous and hazardous.

Desktop research and scientific literature proves that mechanical cleaning is indeed a preferred method of cleaning surgical instruments over mechanical cleaning to ensure reproducible outcomes and reduce potential risks to staff (Alfa M.J et al. 2019; WHO 2016).

Rural Indian hospitals did not use mechanical washers because they are too expensive to purchase, operate and the number of instrument sets to be washed per cycle was too less to economically operate such devices. It was hence only practical for them to reprocess the instruments by hand. During the field visits, only one of the four hospitals owned a washer but was never used for the aforementioned reason (fig 5.5.2). Fig 5.2.3 graphically illustrates the pain points mentioned above.

Fig 5.2.2 Unused washer-disinfector in hospital A

Mechanical Washer -Disinfectors are expensive.

Existing washer disinfectors in India cost ~2500 euro. Rural Indian hospitals are run by trusts and donations.

Demand vast amount of water.

The average washer disinfector uses ~200L of water per batch.

Maintenance and spare parts are not easily found.

Maintenance demands dedicated technicians and spare parts that are not easily available in rural contexts

Machines are produced in HICs.

Products designed and manufactured for HICs are not compatible with LMIC settings.

Lack of instrument sets.

A lack of instruments to clean is inefficient for the operation of a washer disinfector

Fig 5.2.3 Reasons why mechanical systems are not implemented in rural India.

5.3 Defining the Problem

After discovering all the problems in the rural Indian hospital sterile processing practices and scoping down to mechanical cleaning, it is now necessary to define the problem at hand and the subsequent procedures for tackling this problem. The problem definition has been formulated by asking the basic yet inevitable questions:

1) What is the Problem?

Laparoscopic Instruments are very difficult to reprocess in rural Indian hospitals.

2) Who has the Problem?

Nurses have the most trouble with cleaning these instruments because it is their job to clean instruments in rural Indian hospitals.

3) What are the relevant context factors?

Lack of Sterile Processing Department, untrained, under-protected and overworked nurses, underfunded trust hospitals.

4) What are the goals?

The goal of the project is to find frugal methods of assisting the overworked nurses in cleaning the laparoscopic instruments in rural Indian Hospitals.

"The demand for laparoscopic surgeries in rural India has increased to help curb the number of SSI cases due to unsterile operating conditions in rural India. The rate of SSIs can be reduced even more by using sterile laparoscopic surgical instruments however, contextual factors prevent surgical instruments from being reprocessed efficiently leading to the use of unsterile laparoscopic instruments."

The envisioned project outcome is to conceptualize a frugal mechanical washer for effectively cleaning reusable laparoscopic surgical instruments to reduce healthcare-associated infections and alleviate nurse workload in rural Indian hospitals.

5.4 Persona

A persona is a representative of the main user group and is an integral method of visualizing the user group to describe their lives, interests, and frustrations while performing the job at hand. Having a persona provides the reader with an example of the key players of the existing systems and their interaction with newly designed interventions that would focus on making their tasks easy and efficient.

Chapter 4.5 already establishes the rural Indian nurses as the key players in the reprocessing of surgical instruments and all further design directions will take place keeping these nurses in mind. This section is dedicated to an imaginary nurse persona who works at a 30-bed rural hospital in the state of Maharashtra. Her age, background, duties, and frustrations are listed below. She is an amalgamation of data from interviews with rural nurses and surgeons during the field visit.

Asha Patil

Nurse at a rural hospital in Satara.

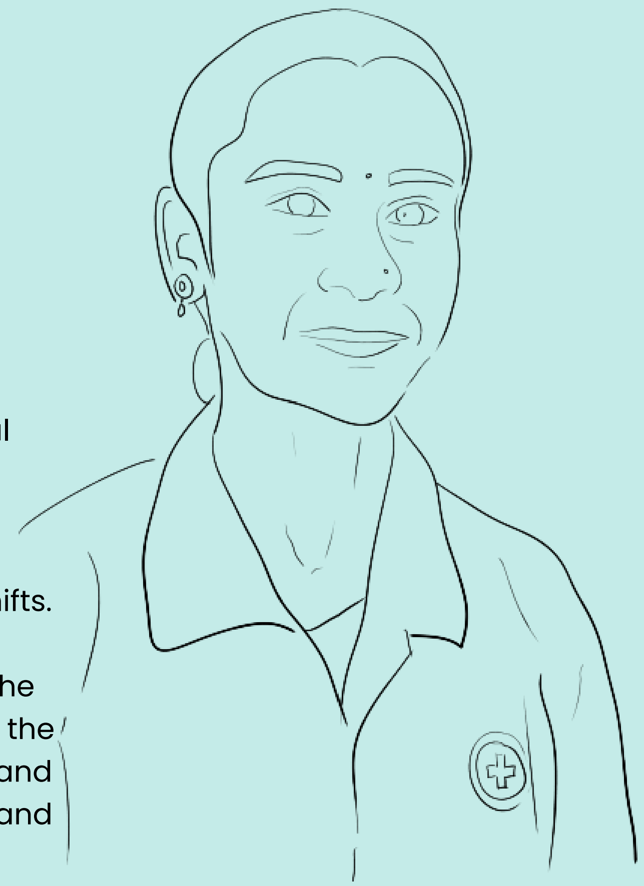
Age: 32 years

Marital Status: Married with two children

Languages: Marathi, Hindi.

Education: Passed high school from local municipal school Satara.

Being a mother of 2, she works hard as a nurse to make ends meet, sometimes working for 12 hour shifts. She has learned how to clean most of the special tools through the surgeon's instructions. At times, she assists the only surgeon of the hospital. She scrubs the soiled instruments after surgery with a toothbrush and detergent powder by hand in a sink beside the OR and only follows the surgeon's instructions.



The barriers and frustrations that prevent her from efficiently reprocessing the soiled instruments are,

- doing all the cleaning by hand which takes up many hours during busy surgery day
- Does not take initiative to learn more about her work
- Does as told to avoid altercations with higher authorities
- Can only communicate in local language.
- she finds cleaning laparoscopic instruments frustrating and time consuming.
- has limited understanding of her job and does not fully understand the repercussions of not completely cleaning the tools.

5 . 5 List Requirements

The research and analysis of surgical instrument reprocessing practices in rural India have led to addressing the need for mechanical washing systems for laparoscopic instruments. Many of the insights and challenges from the previous chapters have been converted to identified requirements in this chapter. The development of a low-cost frugal mechanical washing system should satisfy this list of requirements for it to become a successful device. These challenges will then be systematically divided into clusters that act as a checklist for the device's functionality. A comprehensive list of requirements is listed in appendix E.

Challenge		Requirement
1. The supply of water and electricity is always fluctuating in rural areas.	→	1. The washer should be a standalone device with minimal dependence on hospital infrastructure.
2. Laparoscopic instrument cleaning is done manually with toothbrushes and detergent	→	2. The washer should be able to flush, wash and rinse the laparoscopic instruments.
3. Washers are not used in rural India because the number of instruments needed to fill the device is less.	→	3. The washer should wash 10 graspers, 5 trocars, 1 set of basic surgical instruments and pipes. (fig 4.4.1)
4. Grasper inserts are non luminous with complex hinge geometry.	→	4. The washer should have a separate provision for non lumened instruments and smaller attachments.
5. At present, all surgical instrument cleaning is done by hand which is cumbersome and time consuming to hospital staff.	→	5. The washer should be able to rid the laparoscopic instruments of all gross bioburden.
6. Laparoscopic instruments need to be dismantled before cleaning.	→	6. The washer should have one main chamber with multiple smaller sections for washing dismantled laparoscopic and ancillary instruments.
7. Rural hospitals have to perform as many surgeries as possible with their small instrument inventory.	→	7. The washer should clean the laparoscopic instruments batch within 30minutes.
8. Nurses are constantly exposed to contaminated aerosolized water while manually cleaning the instruments.	→	8. The washer should be fully sealed to prevent splashing and aerosolization of soiled water.

9. Rural hospitals are too underfunded and remote to purchase and rely on expensive spare parts and experts for maintenance. → 9. Spare parts of the washer should be easily available and replaceable.

10. A significant number of rural nurses are women. → 10. The washer should be ergonomically feasible, taking into account average height of Indian females.

11. Most rural nurses are semi- literate and not trained sterile processing technicians. → 11. The washer control panels should be adaptable to local languages

12. Existing surgical instruments are only 70% clean and sterile. → 12. The washer should clean remove atleast 90% of the contaminants on each laparoscopic instrument.

13. Washer Disinfectors are cost almost ~2500euros in India (IndiaMart) → 13. The washer should not cost more than 600 Euro. (fig5.2.3)

14. Existing single chamber washer disinfectors use ~200L of water in every batch of instrments. → 14. The washer should use less than ~200L of water with evey batch.

15. Nurses are very overburdened and short on time because they have to cater to other hospital duties. → 15. The loading of the instruments on the instrument rack should be simple, straightforward and quick

15.1. The effort taken by hospital staff to load the loaded instrument rack in the chamber should be minimum.

15.2. The washer cart should be loaded within 10 minutes.

15.3. The washer should be operated with minimum interaction and vigilance from the hospital staff.

#	KEY PRODUCT REQUIREMENTS
1	The washer should be a stand alone device with minimal dependence on hospital infrastructure.
2	The washer should be able to flush, wash and rinse the laparoscopic instruments.
3	The washer should wash laparoscopic instrument sets that consist of 10 graspers, 5 trocars, 1 set of basic surgical instruments and pipes.(fig 4.4.1)
4	The washer should have a separate provision for non lumened instruments and smaller attachments.
5	The washer should be able to rid the laparoscopic instruments of all gross bioburden mechanically.
6	The washer should have one main chamber with multiple smaller chambers for washing dismantled laparoscopic and ancillary instruments.
7	The washer should clean the laparoscopic instruments batch within 30 minutes.
8	The washer should be fully sealed to prevent splashing and aerosolization of soiled water.
9	Spare parts of the washer should be easily available and replaceable.
10	The washer should clean remove atleast 90% of the contaminants on each laparoscopic instrument.
11	The washer should not cost more than 600 Euro. (fig5.2.3)
12	The washer should use less than ~200L of water with evey batch.
#	**KEY USER REQUIREMENTS**
1	The loading of the instruments on the instrument rack should be simple, straightforward and quick.
2	The effort taken by hospital staff to load the loaded instrument rack in the chamber should be minimum.
3	The washer should be loaded within 5 minutes.
4	The washer should be operated with minimum interaction and vigilance from the hospital staff
5	The washer should be ergonomically feasible, taking into account average height of Indian females.
6	The washer control panels should be adaptable to local languages.

Fig 5.5.1 List of Key Requirements.

6 Develop

The design phase of this graduation project is the amalgamation of the entire discovery and define phase into a final product design deliverable. Evidence through research and observation has proved the need for a frugal and robust mechanical washer for cleaning soiled reusable laparoscopic surgical instruments. The list of requirements and nurse persona reinforce a way to the concept design of the device.

Several techniques were implemented in the design process like brainstorm sessions, creative facilitation sessions, sketching and prototyping for validation. This section is dedicated to shedding light on the stepping stones to the concept design of the device.

6 . 1 Design Drivers

Mentioning the design drivers early on in the design process is integral to control the ideas that arise from the brainstorm and creative facilitation phase. Mentioned here are the principal design drivers for this project that arise from the contextual and user perspective.

Design for Affordability
A frugal mechanical washer that is cost effective to amanufacture, purchase, operate and maintain.

Design for Familiarity
Products that seem familiar and intuitive and do not intimidate the user.

Design for Repairability
Design a frugal device that is easily repairable and supports off the counter locally available spare parts.

Design for Ownership
Design a device that inculcates the sense of pride and ownership in the user.

Design for Manufacturability
Product that can be locally manufactured with locally available materials, tools and skills.

Fig 6.1.1 Important values as concept design drivers.

6.2 Brainstorming

Now that the problem statement, list of requirements, and concept design drivers have been defined, a brainstorming session was conducted to go broad with ideas. This was a group activity. For the task appraisal step, participants were first given a brief explanation of laparoscopic surgery, presented with the instruments to explore, dismantle and discuss among each other, showed a video of the instrument loading in an existing automated washer, and showed comparative images of the instrument reprocessing practices and conditions in LUMC Leiden and rural India. Because the scope and final outcome of the project were already defined, the group conducted an analysis of existing automated washer-disinfectors used in HIC hospitals (appendix F).

After studying every step of the automated washer journey map, How-To statements were used to initiate divergent thinking and generation of ideas. Open-ended questions were asked for every step to generate alternatives to existing systems.

Final outcomes of this session are reached by an amalgamation of the SCAMPER and How-To's tools mentioned in the Delft Design Guide. These tools in combination with each other helped broaden the possibilities and outcomes of the session. Post its with ideas are clustered into Loading, Flushing, and Washing.

Instrument Rack Loading

Flushing

Washing

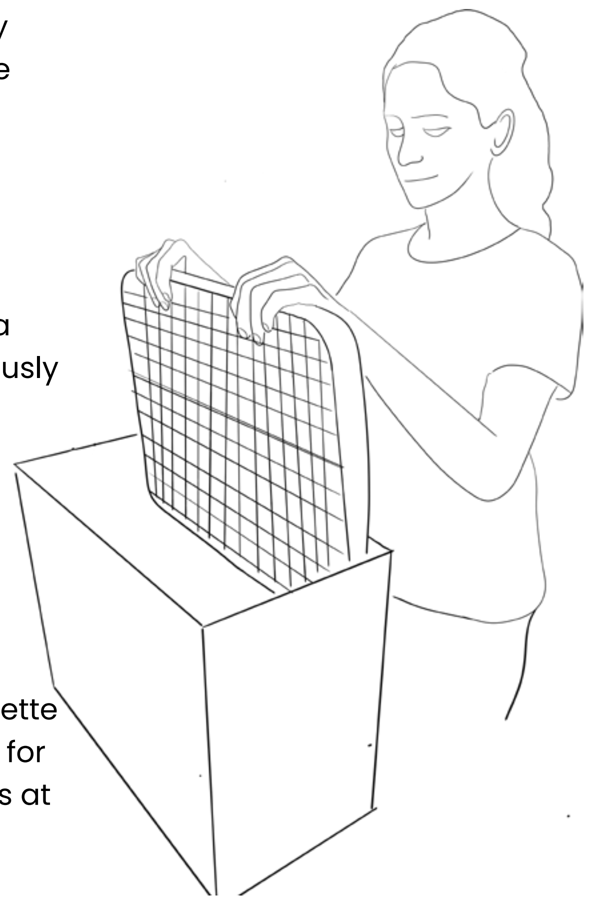
6.2.1 Brainstorm Analysis and Ideation

" Most ideas tended towards substituting existing steps in high end machines with cost effective alternatives to fit the context and the given problem brief."

The participant pool was a mix of engineers, architects, and designers making the outcomes of this brainstorm session wide and diverse. Some ideas were very strong and some less but could be impactful if combined with other ideas. Frugality was of the highest concern and addressed in the very beginning. Most ideas tended towards substituting existing steps in high-end machines with cost-effective alternatives to fit the context and the given problem brief. The clusters that resulted from the brainstorm are analyzed and mentioned in this section of the chapter.

Loading

Instruments racks are the holders where dismantled instruments are mounted for washing. This is the only point of direct physical interaction between the nurse and the washer. Ergonomic factors are significant design drivers for this stage.



- **Instrument Cassette Rack**

This idea is inspired by inserting a VHS cassette into a VCR. Graspers and inserts can be loaded simultaneously onto one cassette. A central pipe that branches out to accommodate Luer locks, irrigation sheaths, and irrigation adapters flush the inside of the lumened instruments.

Pros:
This setup gives the nurse the flexibility to set the instrument cassette as per his/her comfort. The cassette can be loaded elsewhere and brought to the washer for loading. The cassette can help hold all open graspers at the same level for easy mechanical cleaning action.

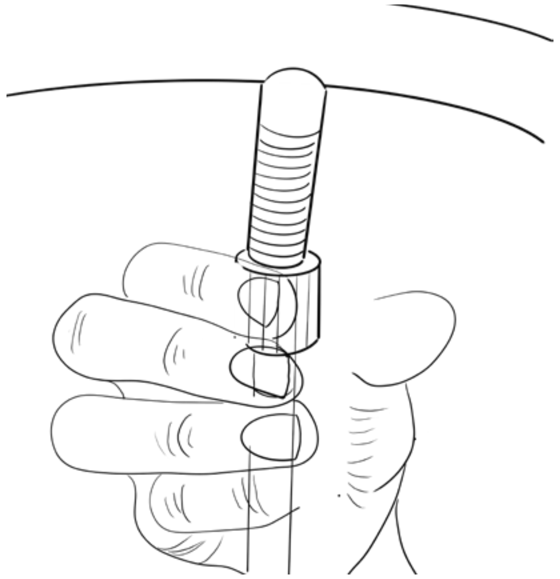
Cons:
The grasper inserts need to be set in the cassette with open jaws. Special care has to be taken to achieve this.

- **Inverted Rack System.**

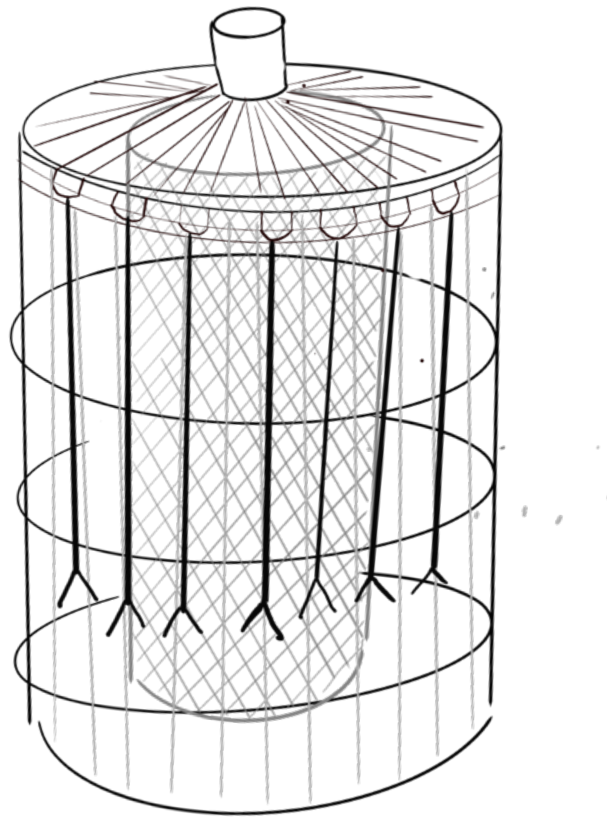
The circular rack design incorporates the main frame of the rack, luer lock nozzles, irrigation sheaths and adapters. The rack is designed in a manner that allows equal distribution of water into smaller capillary nozzles. The instruments hanging from the rack could look similar to a chandelier.

Pros:
The flow of water incorporated due to the instrument orientation is top to down. This avoids the need of high pressure pumps. Use of irrigation sheaths allows a wide variety of instruments to be attached to be cleaned simultaneously. Flushing and rinsing can be achieved by pumping the lumened instruments with water through the irrigation sheaths.

Cons:
Loading the instruments upside down on a circular rack could be cumbersome, making the instruments prone to collapsing and slipping out if not attached to the irrigation adapters properly. This idea could be ergonomically unviable. A provision to introduce detergents into the water flow is required.



Attaching a lumened laparoscopic grasper to the nozzle of the instrument rack.



Proposed idea of the chandelier shaped basket with instruments mounted upside down on the instrument rack.

Flushing

Flushing happens when running water is used to rinse away blood and loose debris from the instrument surface. The mechanisms used for flushing and rinsing could be the same because the primary focus is to use a limited supply of running water to take the contaminants away from the instruments. Some ideas pertaining to flushing are closely related to the design of the instrument rack and orientation.

- **Water jets from the bottom.**

Water under high pressure is to be ejected through nozzles to flush the open upside down instrument graspers and trocars. The nozzles could be designed to force water into lumened instruments from the bottom.

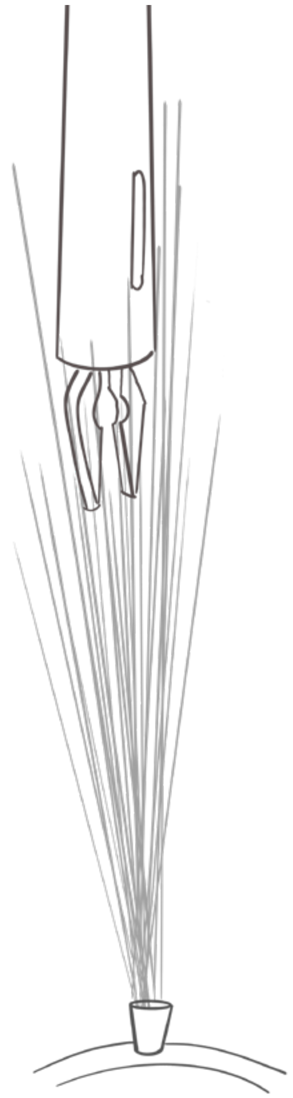
Pros:
This setup allows a wide variety of instruments to be flushed. Water under high pressure due to small nozzles could be effective in impinging the loose debris off the instrument surface.

Cons:
Dependence on high pressure water supply could demands a continuous source of large quantities of water. In rural hospitals, water supply could fluctuate reducing the efficacy of the cleaning process. A workaround to this problem is to combine other methods of cleaning to support the water jets.

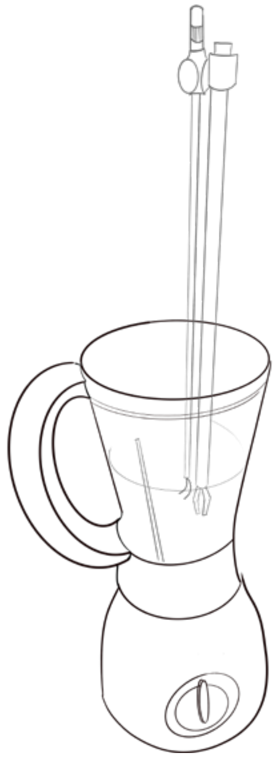
- **Blender Action.**

This idea is inspired by the strong fluid currents produced by a kitchen blender. Open graspers are mounted in the blender chamber upside-down in contact with the detergent solution.The spinning action of the rotor could agitate the water to cause fluid currents flushing the instruments from the outside. Lumened instruments could be flushed from the inside if combined with the chandelier basket concept.

Pros:
This setup implements simple and relatable technology



Proposed idea of having high pressure water sprinklers from the bottom with instruments held upside down (top)



Testing the action of the circular flow of water on soiled laparoscopic instruments.

making it easy to operate and maintain. Laparoscopic trocars, graspers and clip applicators can be flushed and washed simultaneously. Instruments are flushed from the inside the lumen and outside.

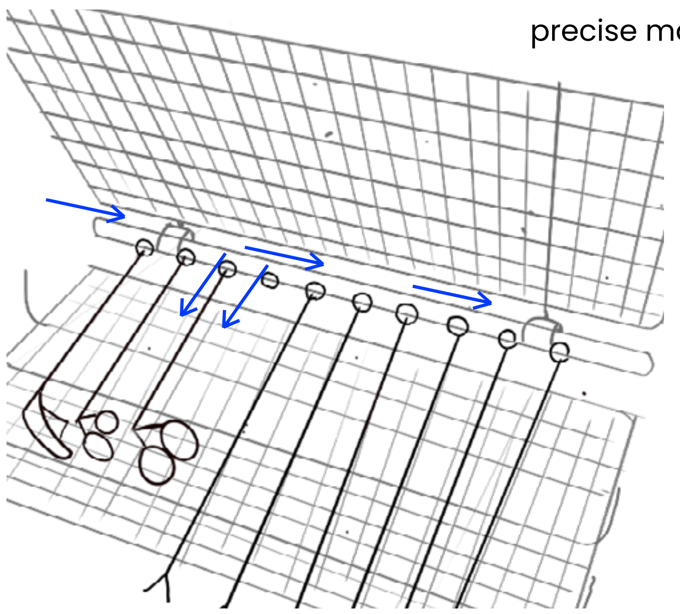
Cons:
The use of powerful motors would prove to be dangerous if loosely attached instruments fall into the spinning rotor. Highest concentration of fluid stresses induced due to the rotation of the water would occur on the inner walls of the drum, servicing the instruments closest to it compared to instruments near the center, reducing the efficacy of this setup.

- **Irrigation through the cassettes racks.**

As mentioned in the Instrument Cassette Loading concept in the previous section, this idea also incorporates removable cassettes. Instruments are attached to a central pipe using luer lock connections and irrigation sheaths of the cassette rack then inserted into the chamber.

Pros:
This setup gives the nurse the comfort to set the instrument cassette with ease. Simple and adaptable design could be cost effective to manufacture, operate and maintain.

Cons:
Construction of these cassettes demand trained and precise manufactuing methods.



Flow of water through the instrument cassette through a central pipe and nozzles

Washing

Ideas related to the washing step are explored here. The primary focus was given to the grasper tips and the insides of trocars because these are the most difficult regions to clean (fig 2.2.1 to fig 2.2.4).

The basic principle of washing is to knock off visible gross surgical debris from instrument surfaces with the help of detergents and impingement. Impingement, caused by fluid shear stress demands the flow of large quantities of running water through minute nozzles at high pressure. As frugality is a driving force of this brainstorm, substitutes for impingement were focused upon. In this case, the simplest substitution to impingement would be mechanical friction. A variety of ideas in relation to fiction with brushes were explored.

“The simplest substitution to impingement would be mechanical friction. ”

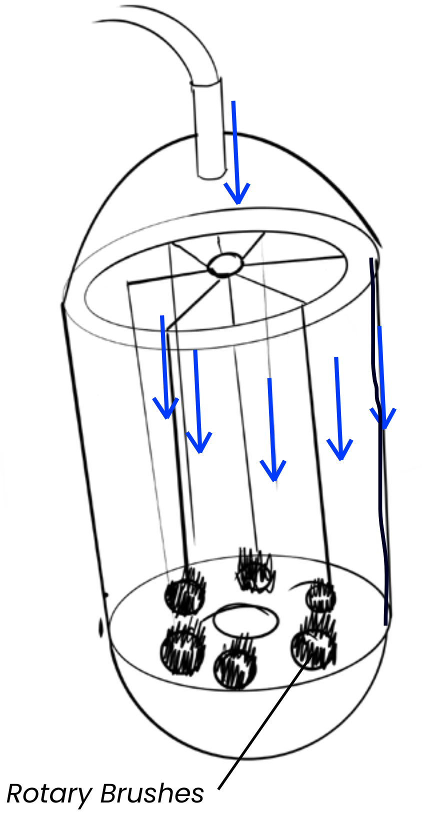
Impingement

Cleans by flushing the instruments with high pressure water jets.

Friction

Cleans by removing contaminants through friction.

A standard washer-disinfector washes instruments with the use of impingement. **Impingement** demands vast volumes of water. If current HIC practices are implemented in rural India, the total amount of water used per day would be **~750 to ~1000L** of water for reprocessing surgical instruments only.



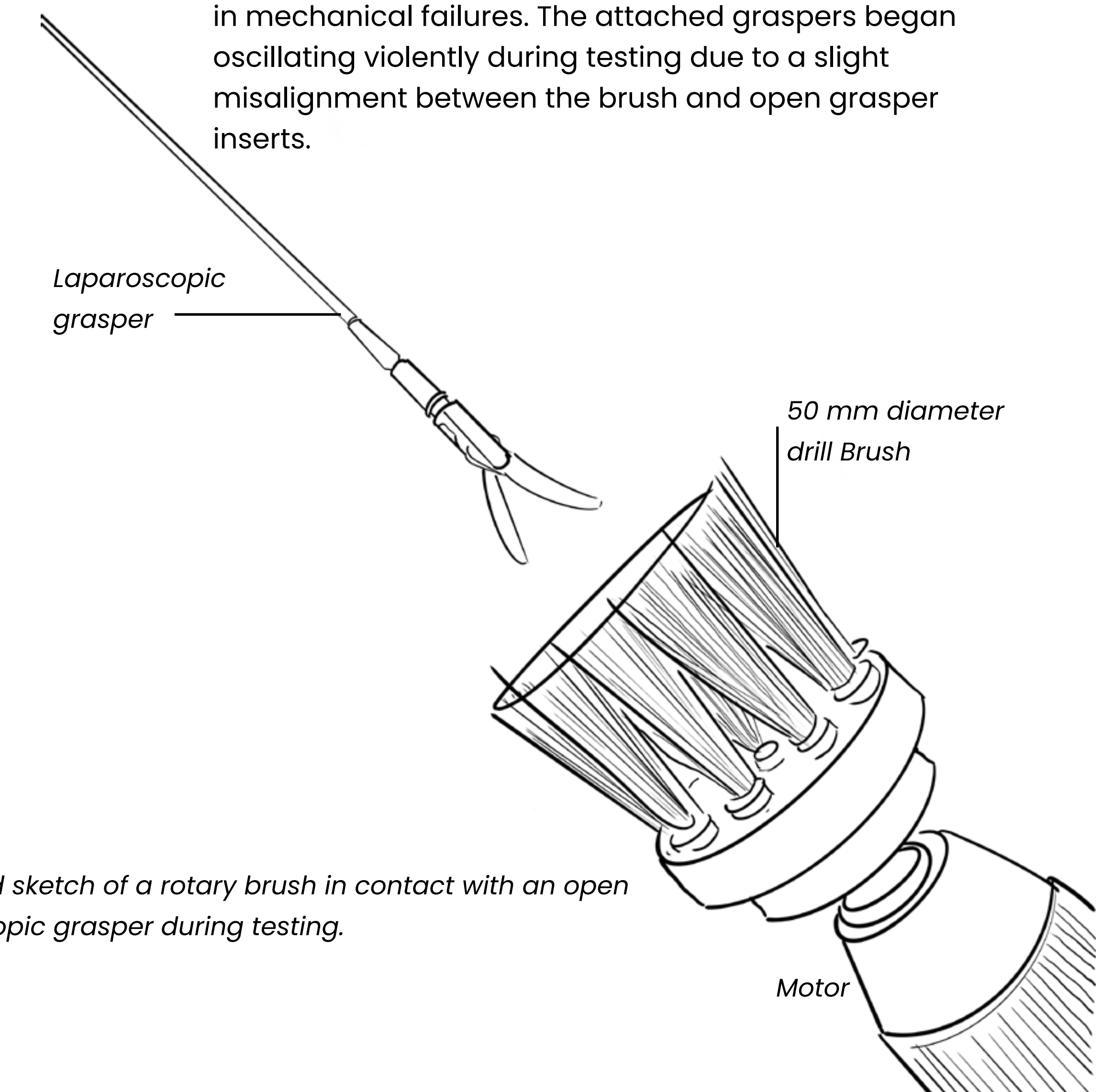
Proposed idea of implementing several rotary drill brushes with laparoscopic instruments held upside down. (top)

- **Rotary Drill Brush**

This idea involves the use of a round drill brush attached to a rotor. The open grasper jaws are in contact with the brush. As the drill brush spins, the friction induced by the brush scrubs the grasper tips. A wide array of these brushes can be mounted by implementing basic engineering principles.

Pros:
With this setup, multiple graspers can be brushed at once. Implementation of simple mechanical engineering principles makes it easy to repair and maintain. The brushes used here are available over the counter in hardware stores in India hence can be easily replaced once the brushes wear out.

Cons:
This setup prevents the brushes from cleaning the grasper hinges and only focuses on the grasper jaws and teeth. If this idea is implemented, the high number of moving parts in the gear arrangement could result in mechanical failures. The attached graspers began oscillating violently during testing due to a slight misalignment between the brush and open grasper inserts.



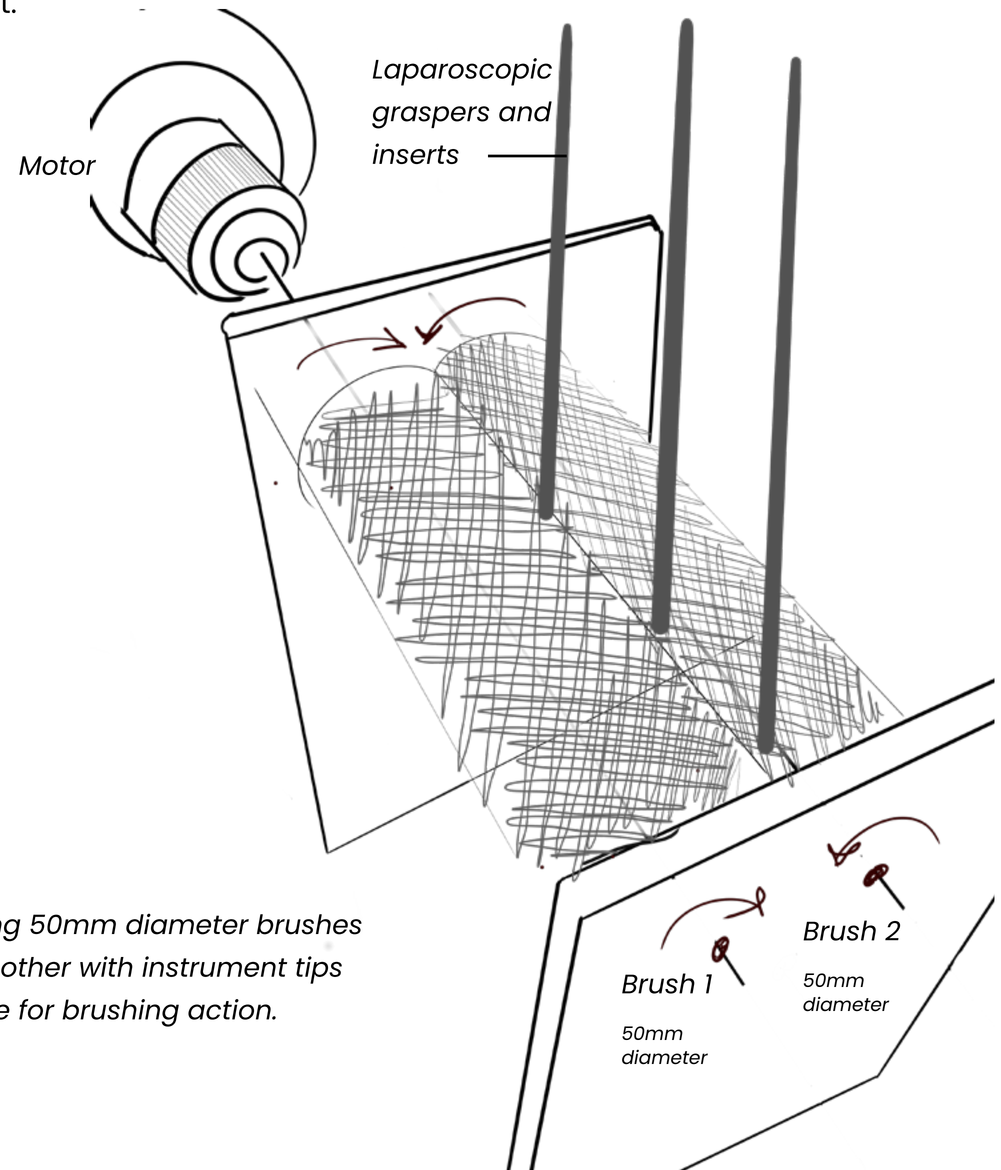
Magnified sketch of a rotary brush in contact with an open laparoscopic grasper during testing.

- **Double Rotary Brushing**

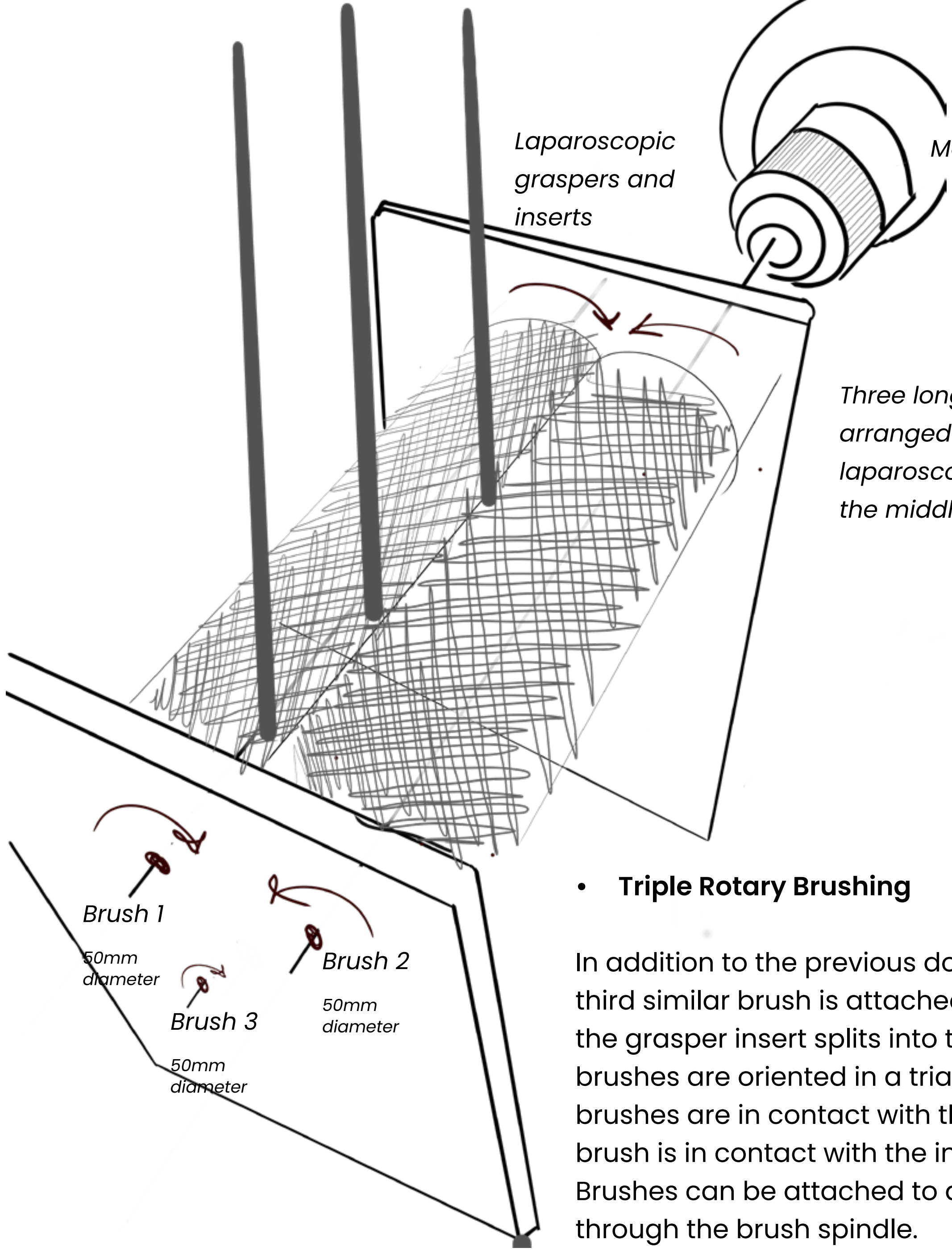
This idea involves the use of two long bottle cleaning brushes to brush the open grasper tips in a rotary manner from either sides of the grasper. Brushes can be attached to and actuated by the motor through the brush spindle. A larger number of instruments can be cleaned simultaneously depending upon the length of the brush. Testing details are mentioned in Appendix H.

Pros:
This setup allows a large array of graspers to be cleaned simultaneously. The brushes implemented in this setup are cheap, widely available and can be easily replaced. The versatility of this brushing method can accommodate a wide variety of instruments.

Cons:
The rotary brushes do a great job in cleaning the sides of the grasper hinges but do not reach the open grasper jaws. This is a major drawback as cleanliness of the jaws is equally important.



Two long and rotating 50mm diameter brushes in contact with each other with instrument tips inserted in the middle for brushing action.



Three long and rotating brushes arranged in a triangular profile with laparoscopic instruments inserted in the middle for brushing action (right).

- **Triple Rotary Brushing**

In addition to the previous double rotor brushes, a third similar brush is attached at the junction where the grasper insert splits into the jaws. In this setup, the brushes are oriented in a triangular pattern where two brushes are in contact with the grasper hinge and one brush is in contact with the insides of the grasper jaw. Brushes can be attached to and actuated by the motor through the brush spindle.

Pros:
This setup allows grasper inserts to be cleaned from three separate points. The brushes interlock into each other causing a stronger effect of friction when anything is inserted between them. The setup allows a large array of graspers to be cleaned simultaneously. The brushes implemented in this setup are cheap, widely available and can be easily replaced. The versatility of this brushing method can accommodate a wide variety of other instruments.

Cons:
This idea demands the use of one extra brush.
Even though the brushes are very cheap and easily available, this setup demands extra attachments to accommodate the third brush.

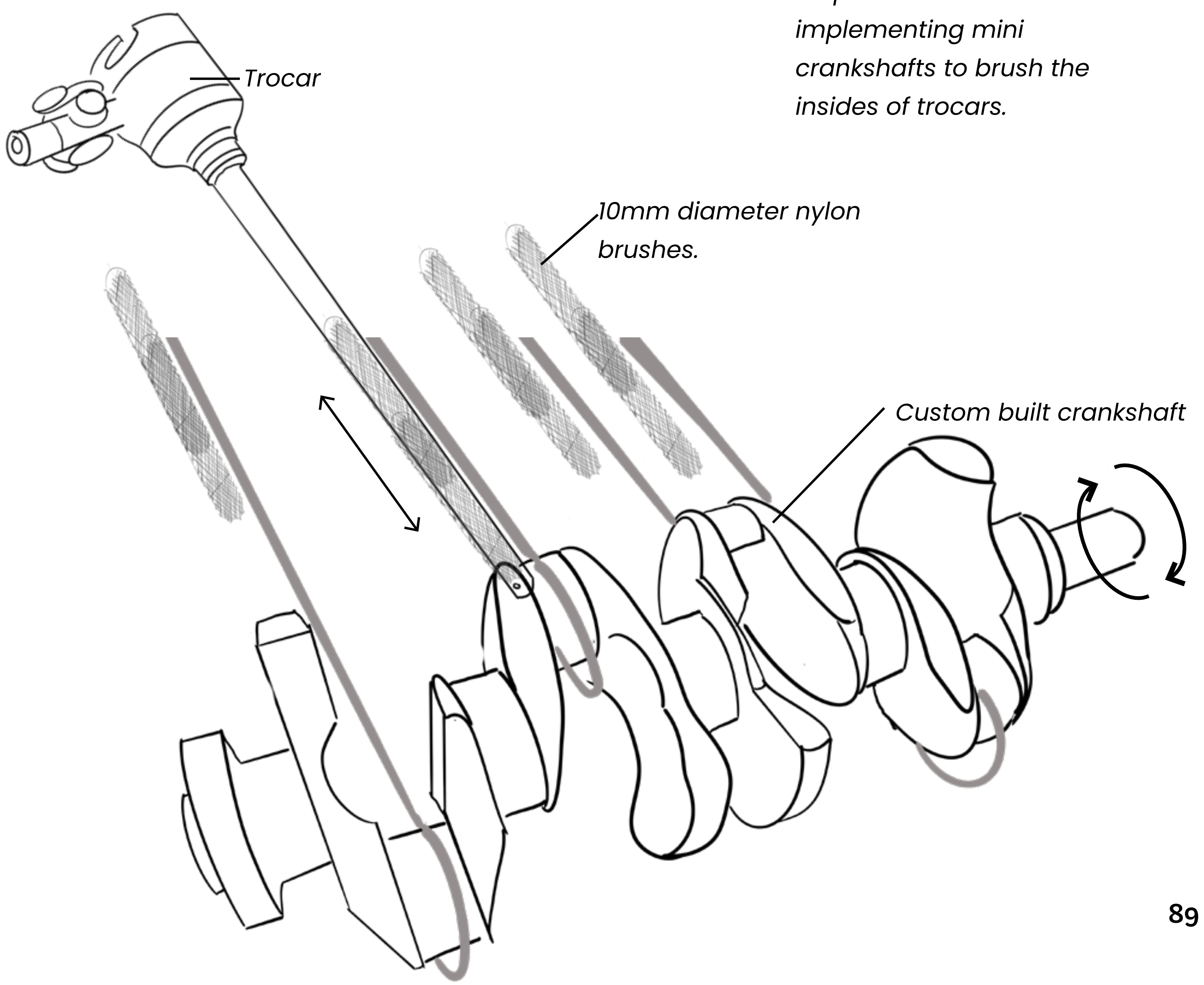
- **Trocar Cleaning**

Trocars long and slender, hard to reach tubular build makes it especially difficult to clean manually. Through testing, it is clear that inserting and oscillating a brush up and down has cleaned the trocar well. To replicate this oscillatory motion, inspiration was taken from the crankshafts of engines (appendix G). Due to time constraints, other methods of trocar brushing were not explored.

Pros:
This is a simple and relatable setup with minimum moving parts. This helps ease the issue of maintenance and failure of the device. The brushes this setup demands is easily available in hardware stores in India.

Cons:
This setup demands a custom built crankshaft which may be very hard to come by incase replacement is necessary. The complex design of the crankshaft itself makes it difficult to clean periodically.

Proposed idea of implementing mini crankshafts to brush the insides of trocars.



6.2.2 Idea Selection

The brainstorm generated a variety of ideas in the three clusters. It is necessary to make the most promising selections from each section to incorporate in the final design of the frugal mechanical washer for rural Indian hospitals.

The Delft Design Guide suggests a vast variety of methods and protocols to help make the most educated decision from a pool of ideas. For this graduation project, the use of testing, prototyping, and Harris profile has proven to be most effective.

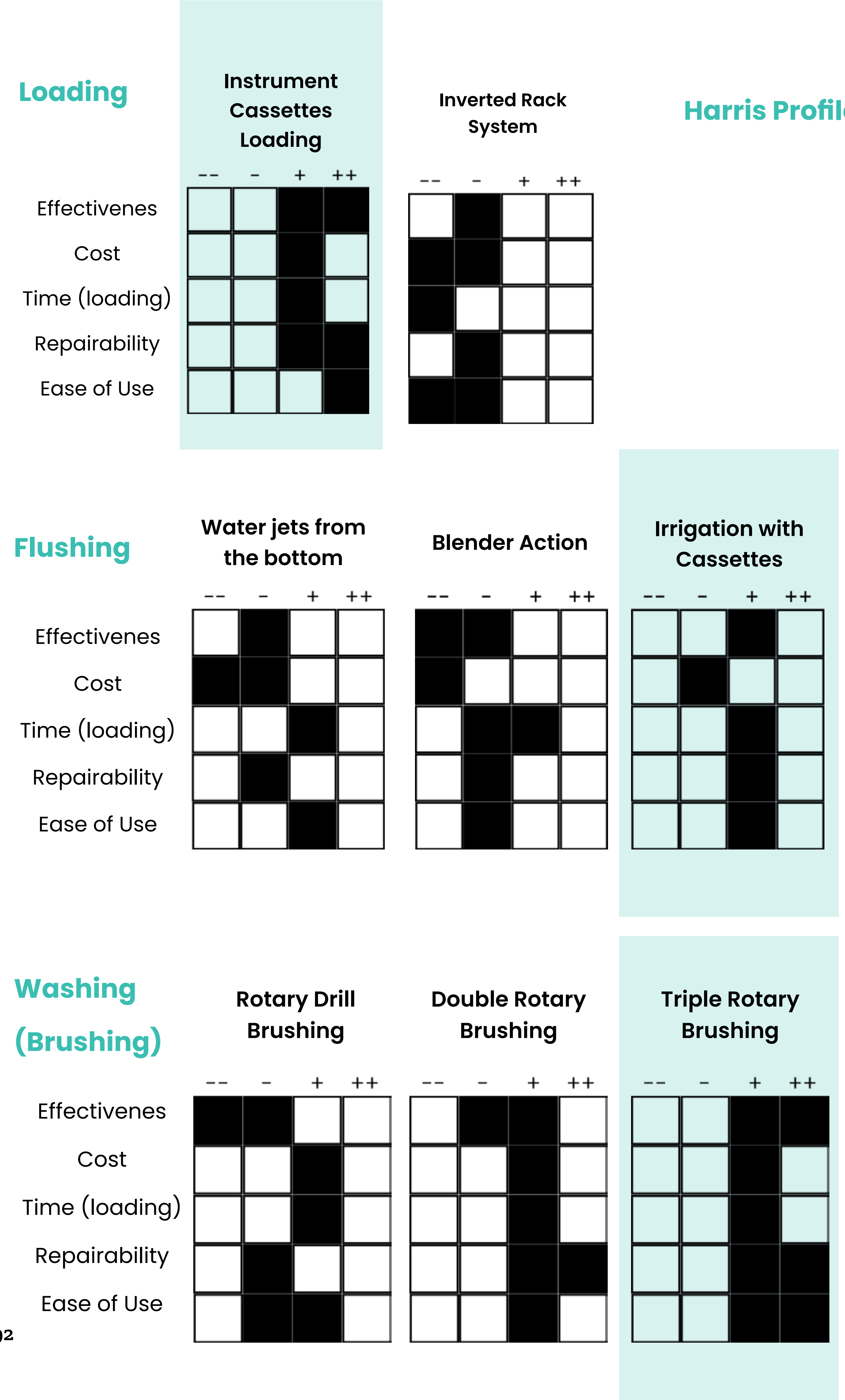
Tests and prototypes emphasized in Appendix G were conducted to evaluate the "Loading" and "Washing (brushing)" stages of the device. Flushing was hence incorporated when the final design of the "Loading" stage was confirmed. This section is focused on the task of making the right decision for the proposed mechanical washer's sub-functions.

All concepts are placed beside each other and weighed according to a set of criteria. The winning concept must fit the said criteria in order to be incorporated for the final design.

The criteria used to weigh the concepts are

1) effectiveness,
2) cost,
3) repairability,
4) ease of use, and
5) time.

- **Effectiveness** in this case is the measure of efficacy of the loading and cleaning concepts. Most concepts have undergone live testing, mentioned in detail in appendix G. Effectiveness in cleaning is the most significant factor for weighing the ideas.
- **Cost** could be the most limiting factor for all LMIC hospitals. A high cost would significantly reduce the chances of implementation of the idea in the design. This criteria focuses on the projected cost of the device and daily running costs.
- **Repairability** and ease of availability of spare parts plays an important role in restoring the life and functionality of the device. Ideas that implement off the counter components would fare higher in preference.
- **Ease of use** is a self explanatory criteria that focuses on the ease or complexity of a certain idea in terms of the nurse's interaction with a subfunction. Rural Indian nurses being strapped on time and under-trained require a design intervention that is quick and simple to implement.
- **Time**. The quick successions at which surgeries take place in rural India make time a crucial factor that determines the usage of this device. This washer is primarily being designed to alleviate nurse's workload and free their time for other pressing hospital duties.



Harris Profile

6 . 3 Analysis of Harris Profile

The output from Harris profiles is the strongest idea in comparison with others in the same cluster. The ideas were tested and weighed through physical prototypes as the primary method of verification (appendix G).

From the Loading category, loading of instruments on a separate cassette before inserting them together into a washer chamber received the highest score. This method is a simple and effective method of loading the instruments. A method of implementing a separate cassette system into the design provides much-needed simplicity and flexibility. The flushing category is directly attached to the rack design and implemented into the cassette design through water pipes and capillary channels.

For the Washing category, it has already been established that brushing is a more effective method of cleaning (appendix H) that does not depend on large volumes of water and high-pressure pumps. Through extensive testing and prototyping as mentioned in Appendix H, a triple rotor rotary brush system has proven to be the most effective of all ideas. This concept also proves to be easy to repair and replace components. Brushes used in this setup can be purchased from many local hardware stores.

6 . 4 Conclusion

The Develop phase of the project has been that of divergent exploration and making critical design decisions substantiated with extensive testing and prototyping. Discussions with members of other technical domains helped broaden choices that helped substitute and disrupt certain facets of existing systems that may not be appropriate for the rural Indian hospital setting. The brainstorm session was divided into three clusters, loading, flushing, and washing. This has helped in the exploration of ideas in three different domains. Similar to a set of Lego, final ideas from the three clusters will be pieced together to create a prototype of the frugal mechanical washer to clean laparoscopic instruments in rural India.

The Harris Profile is an important tool to weigh the feasibility of each concept cluster. Through this exercise, it is clear that the proposed mechanical washer is loaded with the help of cassettes that are removable and can be loaded separately at the nurse's convenience.

7 Deliver

7 . 1 Introduction

The Deliver phase is the final and converging phase of the design project. The design outcome arising from the previous phases of the project is discussed here. Each concept generated during the brainstorm was already physically prototyped and tested to evaluate the most promising concept (Appendix G, H). The goal of this section is to piece together the ideas to form a fully defined concept in the form of a 3D model with renders of the frugal mechanical washer for rural Indian hospitals. Similar to the brainstorm session, this phase is also divided into the aforementioned three clusters Loading, Flushing, and Brushing (fig 7.1). In order to gauge if the frugal mechanical washer has satisfied all the requirements, the table mentioned in chapter 5.5 is later used as a checklist. The CES Edupack is an integral tool and has been consulted for choosing materials for this device's construction and cost estimation. To communicate the overall use case and interaction of the user with the frugal washer, a usage storyboard is created.

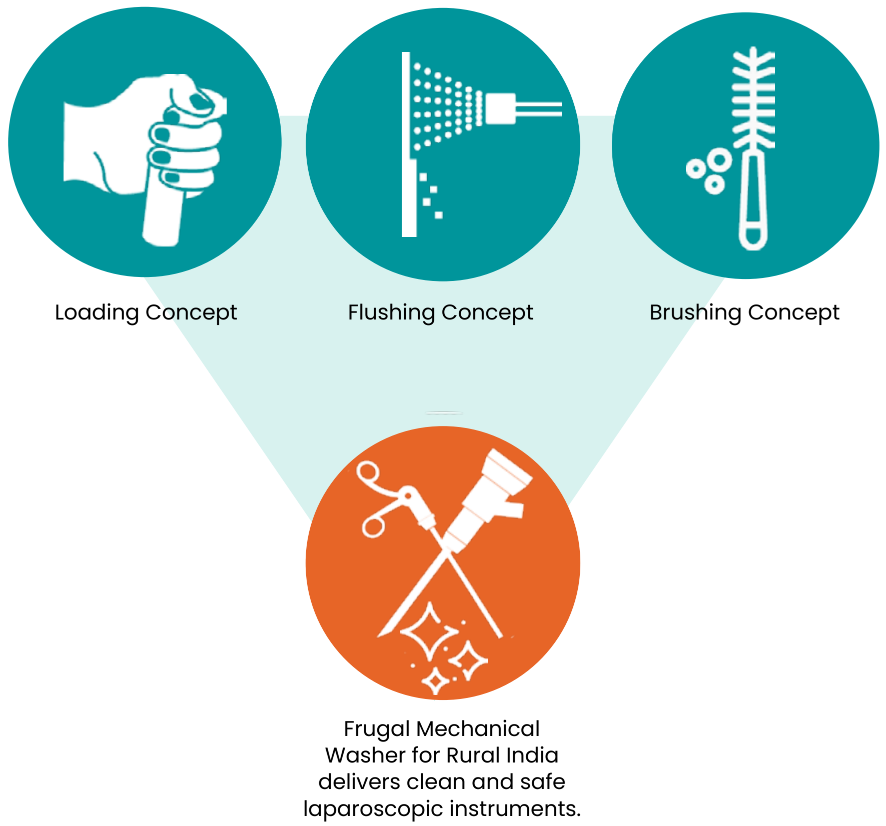


Fig 7.1 Three clusters form one concept design.

7 . 2 Instrument Cassette Detail

As per the concept evaluation, the concept of loading dismantled surgical instruments in a metal mesh cassette was chosen to be the most viable concept. This setup can make loading the soiled and dismantled laparoscopic instruments into the washer easy, comfortable and convenient. The operation of this cassette is simple.

The cassette is an austenitic stainless steel welded metal mesh attached to a central 20mm diameter steel pipe. The pipe allows water flow through to the irrigation nozzles and also acts as a spine for the cassette which bears the load of the instruments and the handle for grabbing.

The primary role of the cassette is to hold the dismantled laparoscopic graspers and inserts. The mesh is designed to allow the grasper tips to be exposed to the brushes inside the washer chamber.

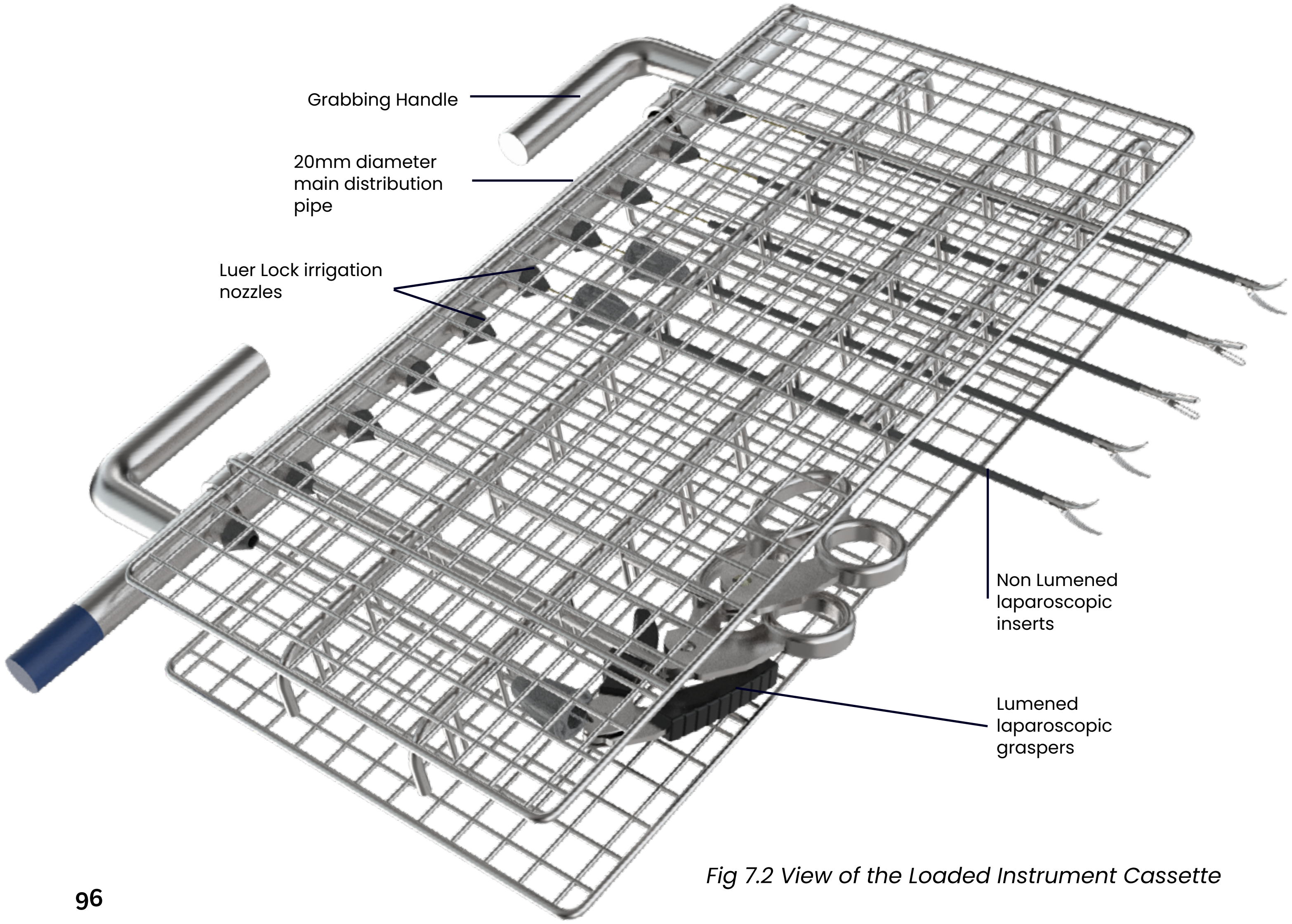


Fig 7.2 View of the Loaded Instrument Cassette

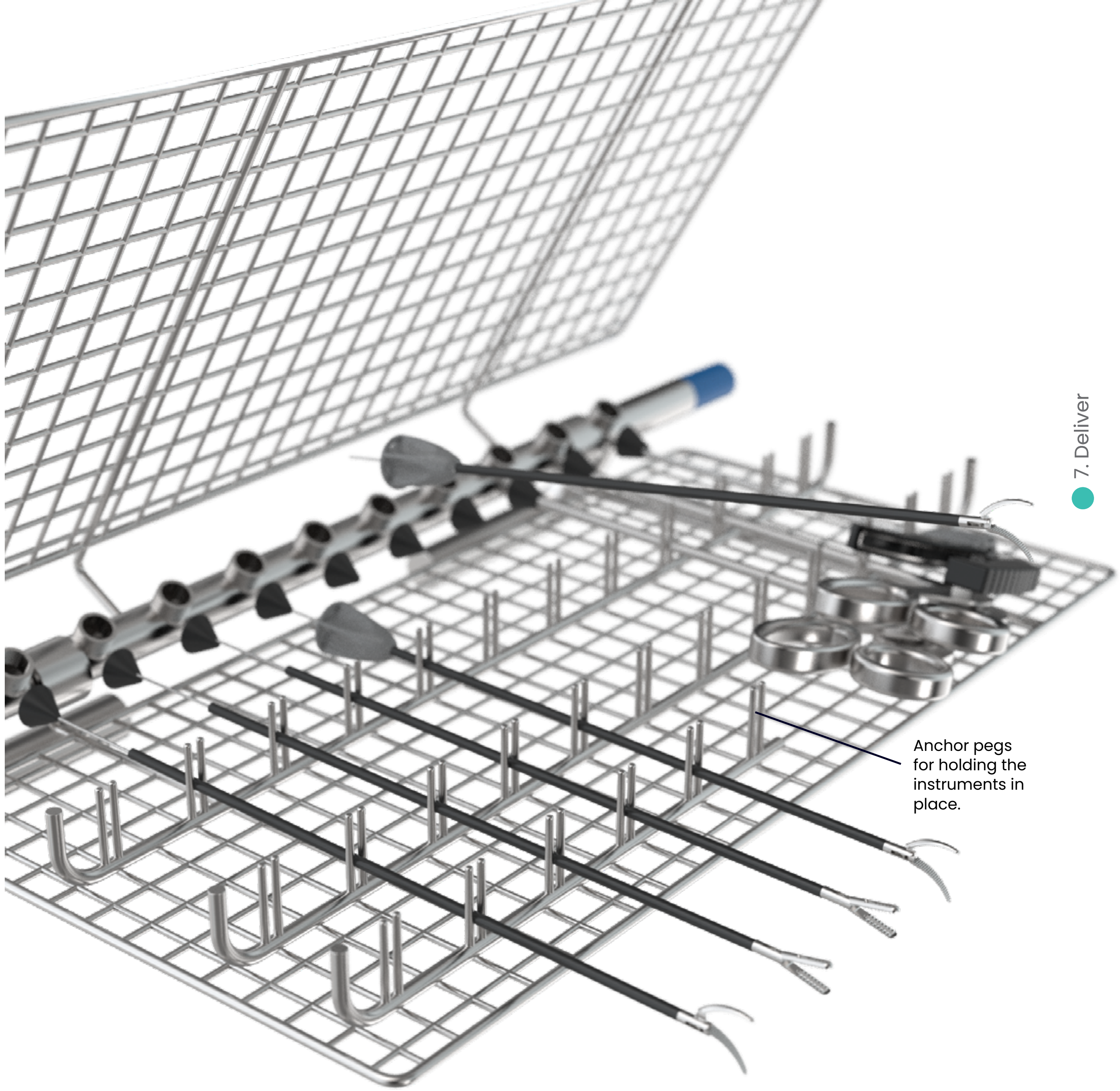
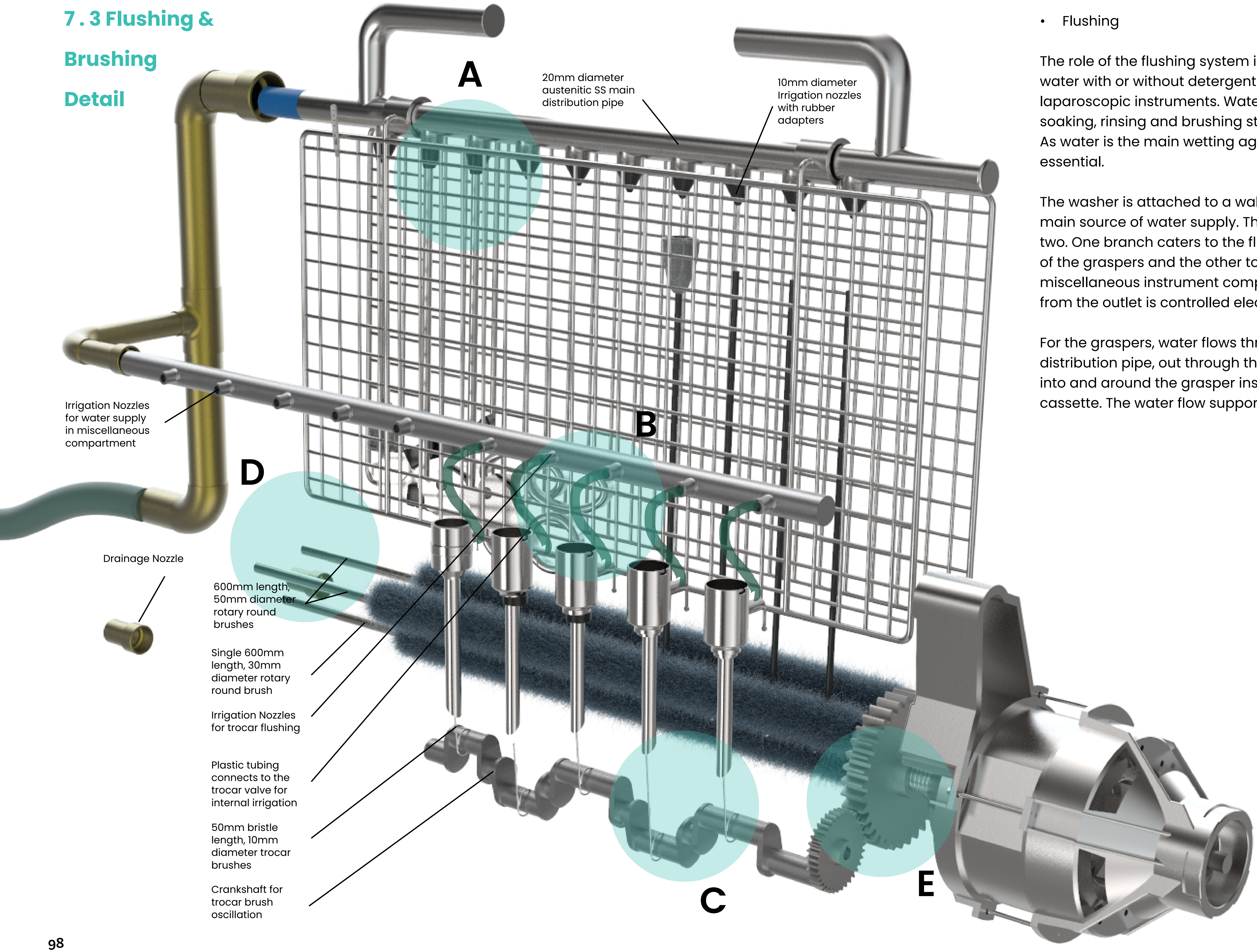


Fig 7.3 View of the Opened and loaded Instrument Cassette

7 . 3 Flushing & Brushing Detail



- Flushing

The role of the flushing system is to provide running water with or without detergent for cleaning the soiled laparoscopic instruments. Water is required for the soaking, rinsing and brushing stages of this device. As water is the main wetting agent, reliable supply is essential.

The washer is attached to a wall outlet pipe that is the main source of water supply. The pipe is branched into two. One branch caters to the flushing and irrigation of the graspers and the other to the trocar and miscellaneous instrument compartment. Water flow from the outlet is controlled electrically through valves.

For the graspers, water flows through the 20mm distribution pipe, out through the leur lock nozzles and into and around the grasper inserts hanging from the cassette. The water flow supports the brushing action.

Fig 7.4 View of the internal mechanism of the washer.

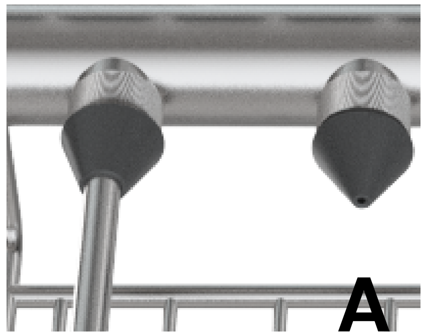
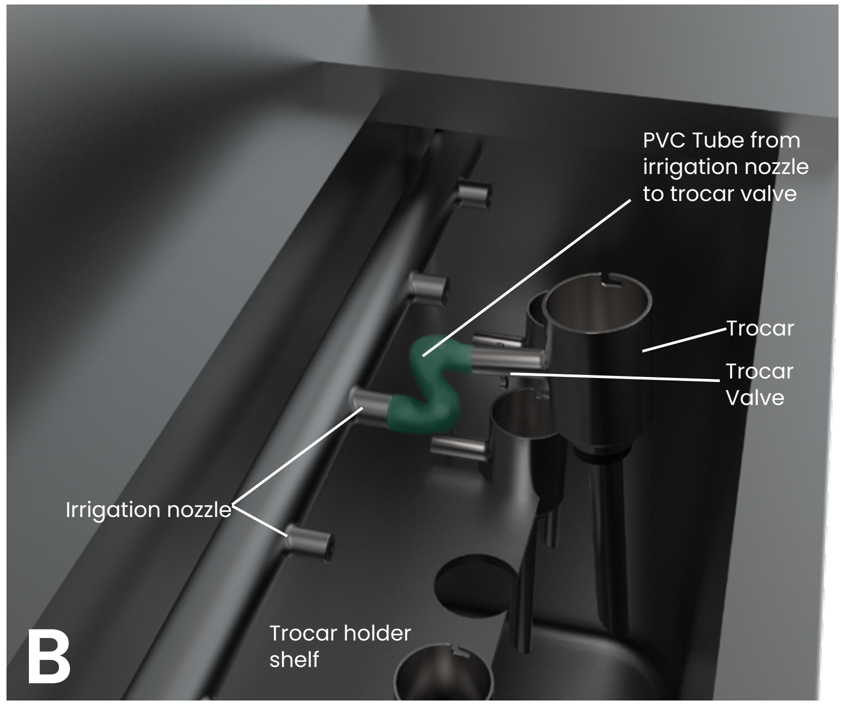


Fig 7.5 View of the irrigation nozzles.

Fig 7.5 gives a clear description of the irrigation nozzles attached to the main 20mm distribution pipe. The nozzles have threading on the inside and outside to accommodate luer lock connections. For instruments without a scre mechanism, rubber sheaths with the help of anchor pegs on the cassette mesh hold the instruments in place. The nozzles are welded to the distribution pipe.

Fig 7.6 The second branch of the distribution pipe transfers water to the trocar compartment. The trocar compartment has five irrigation nozzles that connect to the trocar valve via PVC tubing.

The trocars are placed in the washer by inserting the brush first then connecting the tubes. A metallic holder holds the trocars in place during the crankshaft brushing action



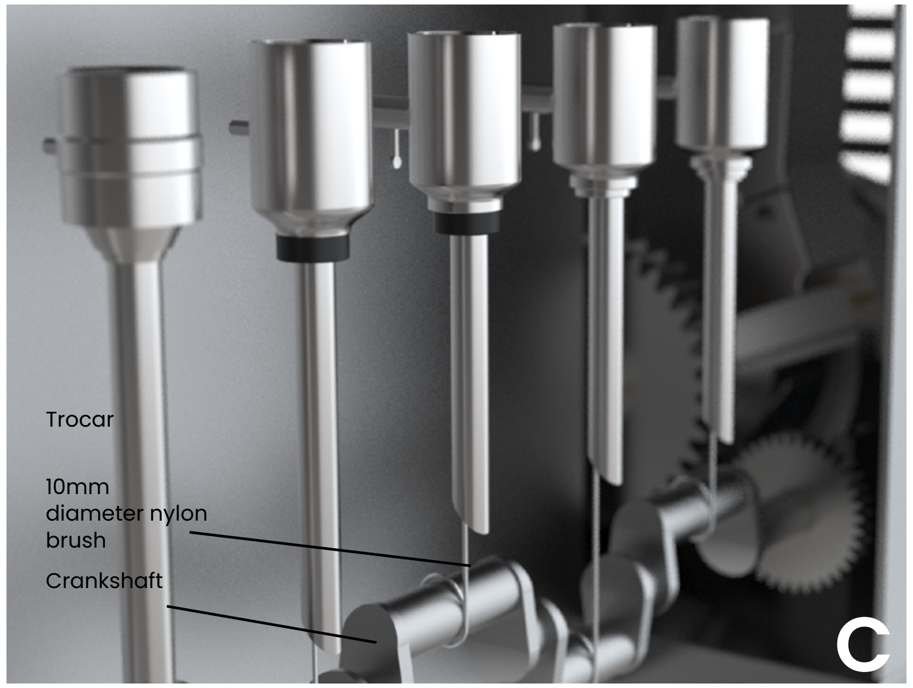


Fig 7.7 This custom built crankshaft has connecting rods of 16mm diameter. 10mm diameter brushes are held by the connecting rods for internal trocar brushing (appendix G).The crankshaft is actuated by the motor. Brushing action for the trocars is 3 minutes.

Fig 7.7 Brushing the trocars with the crankshaft assembly in the trocar compartment.

Fig 7.7 Industrial grade nylon brushes of 700mm length are used for brushing the graspers. One of the three brushes are attached to the motor. The others spin due to a gear arrangement.

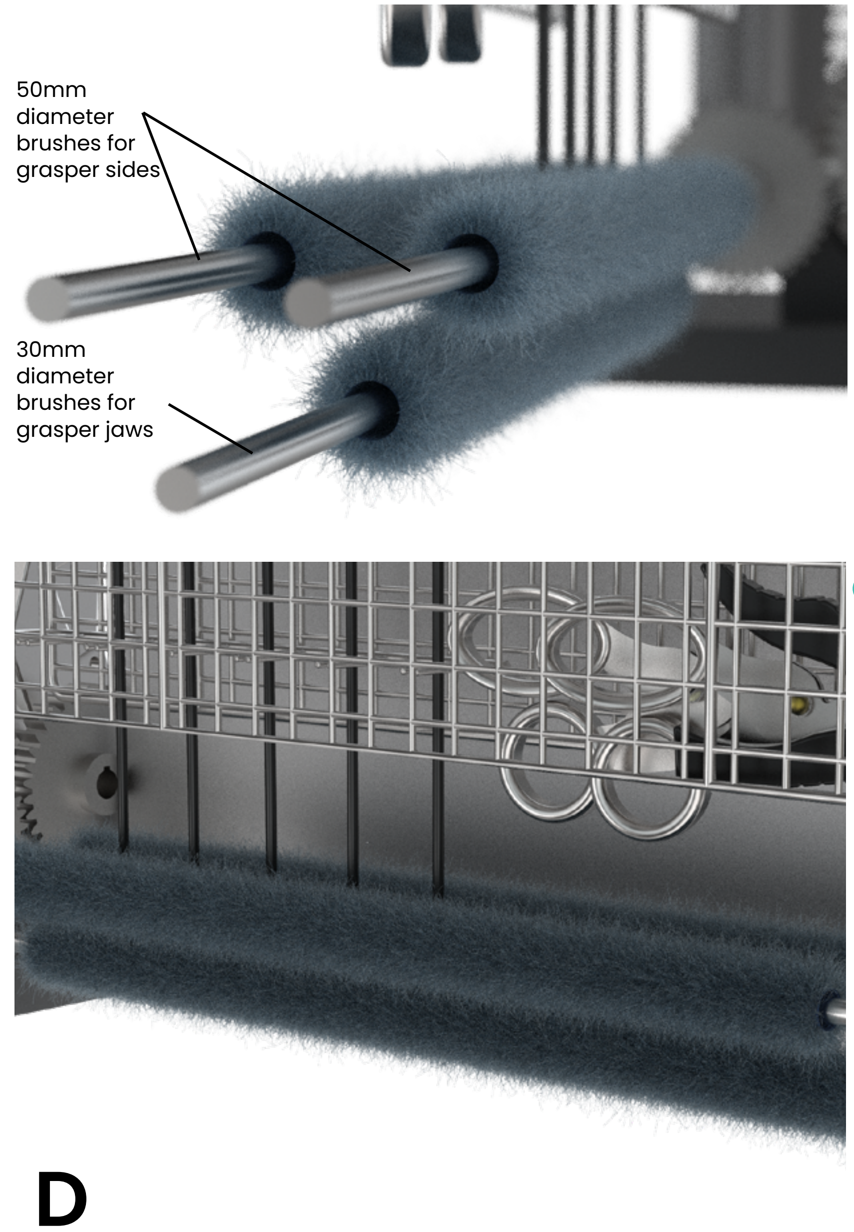


Fig 7.7 View of the grasper brush spindles (top).
Fig 7.8 Side profile of the grasper brushes (bottom)

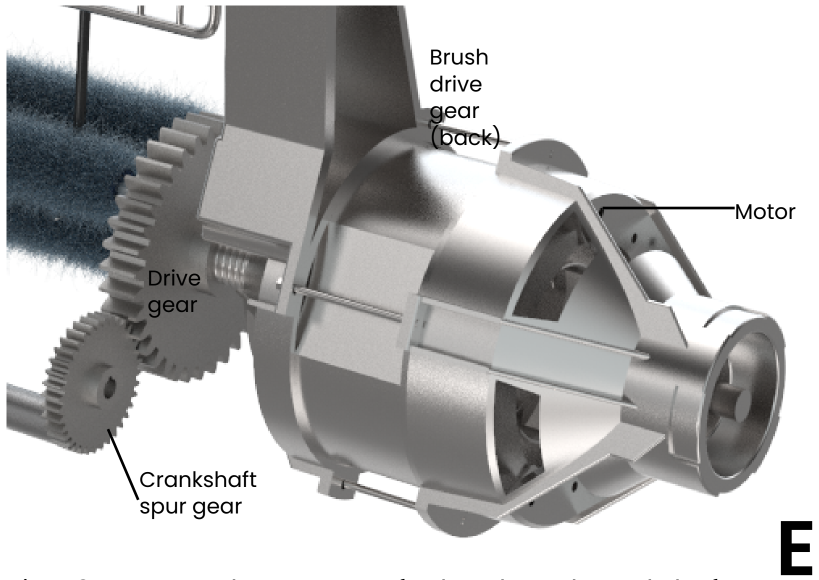


Fig 7.9 Motor and spur gears for brush and crankshaft actuation.

The frugal mechanical washer utilizes a high torque low speed washing machine motor. The spur gear attached to the motor actuates the brush and crankshaft. Speeds of the brushes and crankshaft are yet to be calculated for gear diameter ratios and subsequent RPM.

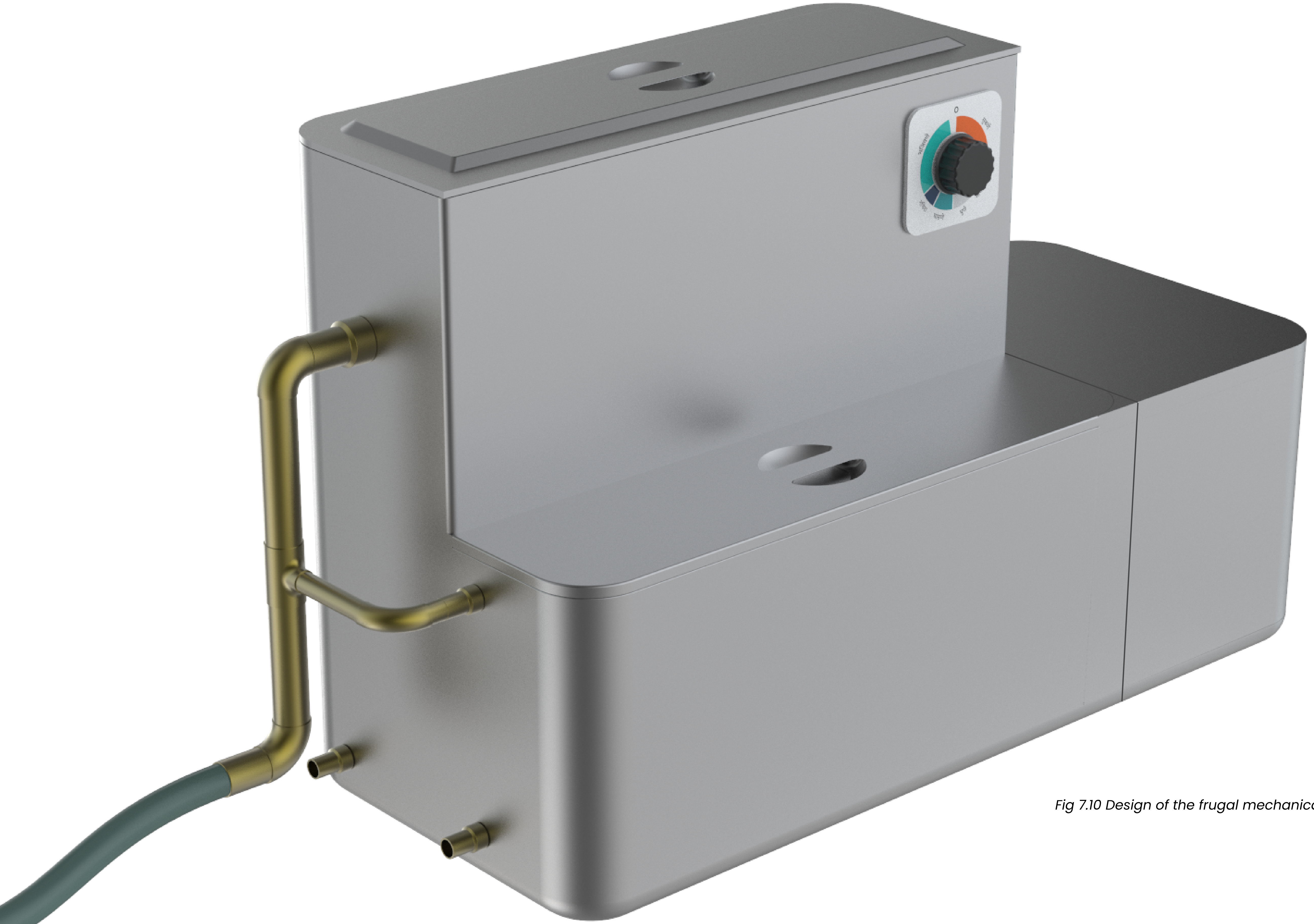


Fig 7.10 Design of the frugal mechanical washer body.

7 . 4 Cabinet Design

The cabinet is the outer shell of the frugal mechanical washer. This cabinet holds all the components, mechanical parts, electronics, water, and surgical instruments inside it. This section explores the outer cabinet design of the frugal mechanical washer.

The cabinet is designed with curved edges to prevent metal cracking and fractures. This makes the device robust, resistant to rough use, and resistant to mechanical stresses on the metal due to thermal action. The washer cabinet is manufactured using **austenitic surgical grade stainless steel** to prevent instances of corrosion and reaction with blood, bodily fluids, hard water, and detergents. The curved corners on the compartment interior allow easy periodic cleaning and prevent the accumulation of debris. Fig 7.10 and 7.11 display the front and top elevation of the frugal washer.

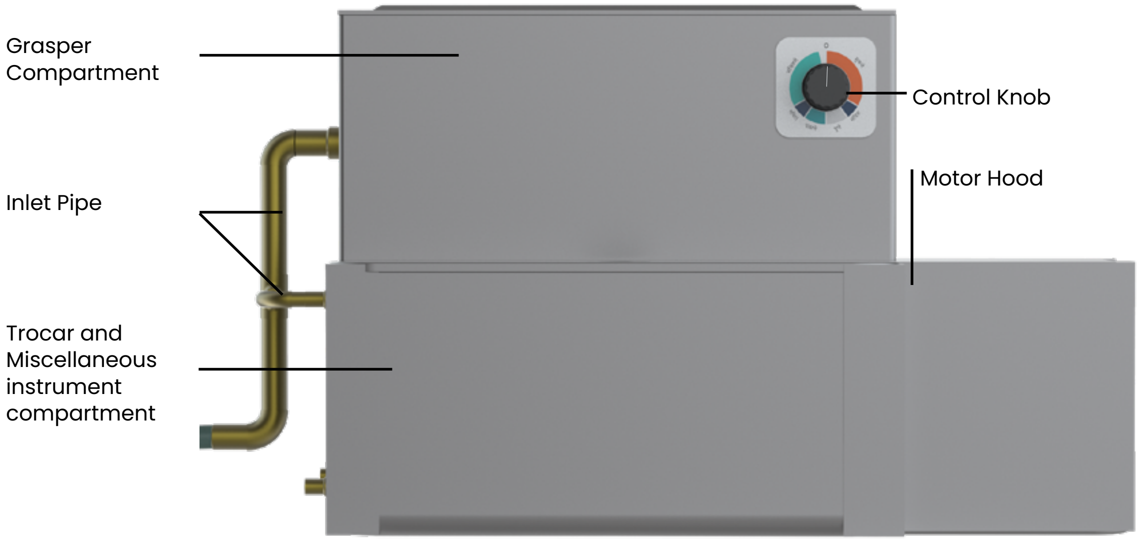


Fig 7.11 Front elevation of the mechanical washer body

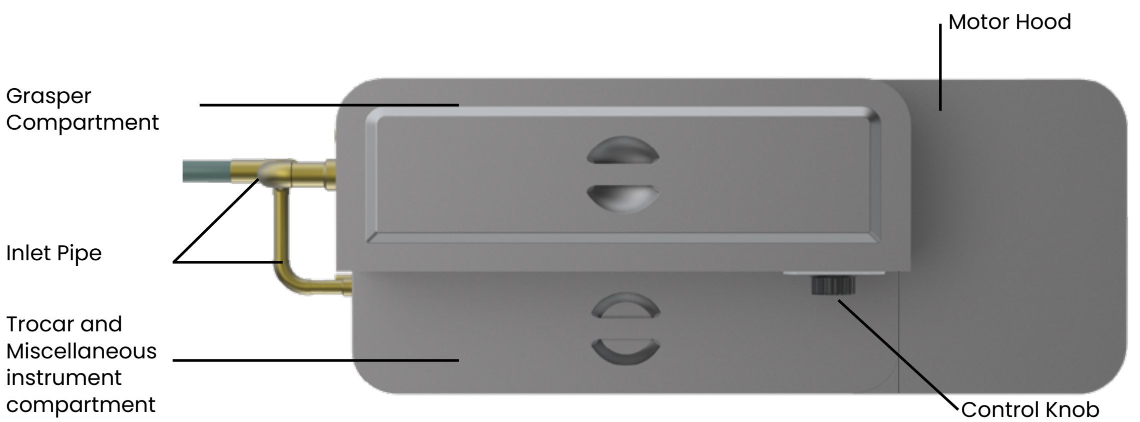


Fig 7.12 Top elevation of the mechanical washer body

Fig 7.13 View of the lid

The lids of the compartments are also made of austenitic surgical grade stainless steel. Indentation in the lid accommodates for easy gripping and lifting action with minimum contact with the lid. The lids are internally lined to prevent leaking of aerosolized water during the brushing and rinsing. The lid also prevents dust and foreign particles from entering and contaminating the compartment.

Fig 7.14 Proposed idea of sliding the cassette into the compartment

2mm thick austenitic stainless steel is used for the construction of the cabinet. To impart stiffness and insulation between the inner and outer walls of the cabinet a 20mm gap is provided. This insulates the outer wall from the inner wall which is subject to heat and vibrations.

The slide rails on the inner wall of the cabinet help the nurse guide the cassette into the compartment with ease prevented the loaded cassette from misaligning in the washer.

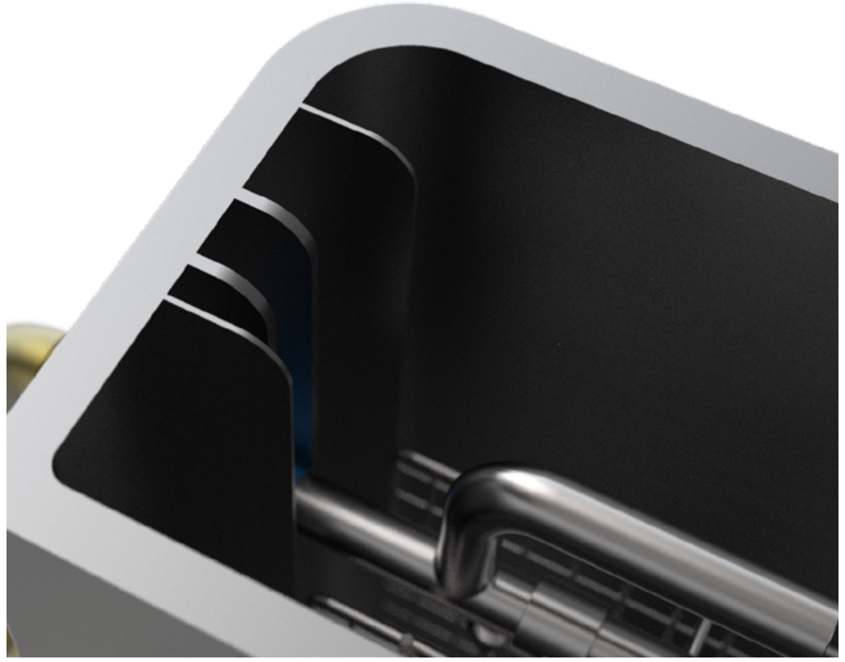


Fig 7.15 Slide railing for cassette

The mechanical washer covers an area of 880mm X 430mm and hence can be placed atop a table or counter for easy use. Keeping it on a table makes it comfortable for the nurse to load, unload and interact with the device. Fig 7.15 shows the size of the washer as compared to an average Indian height.

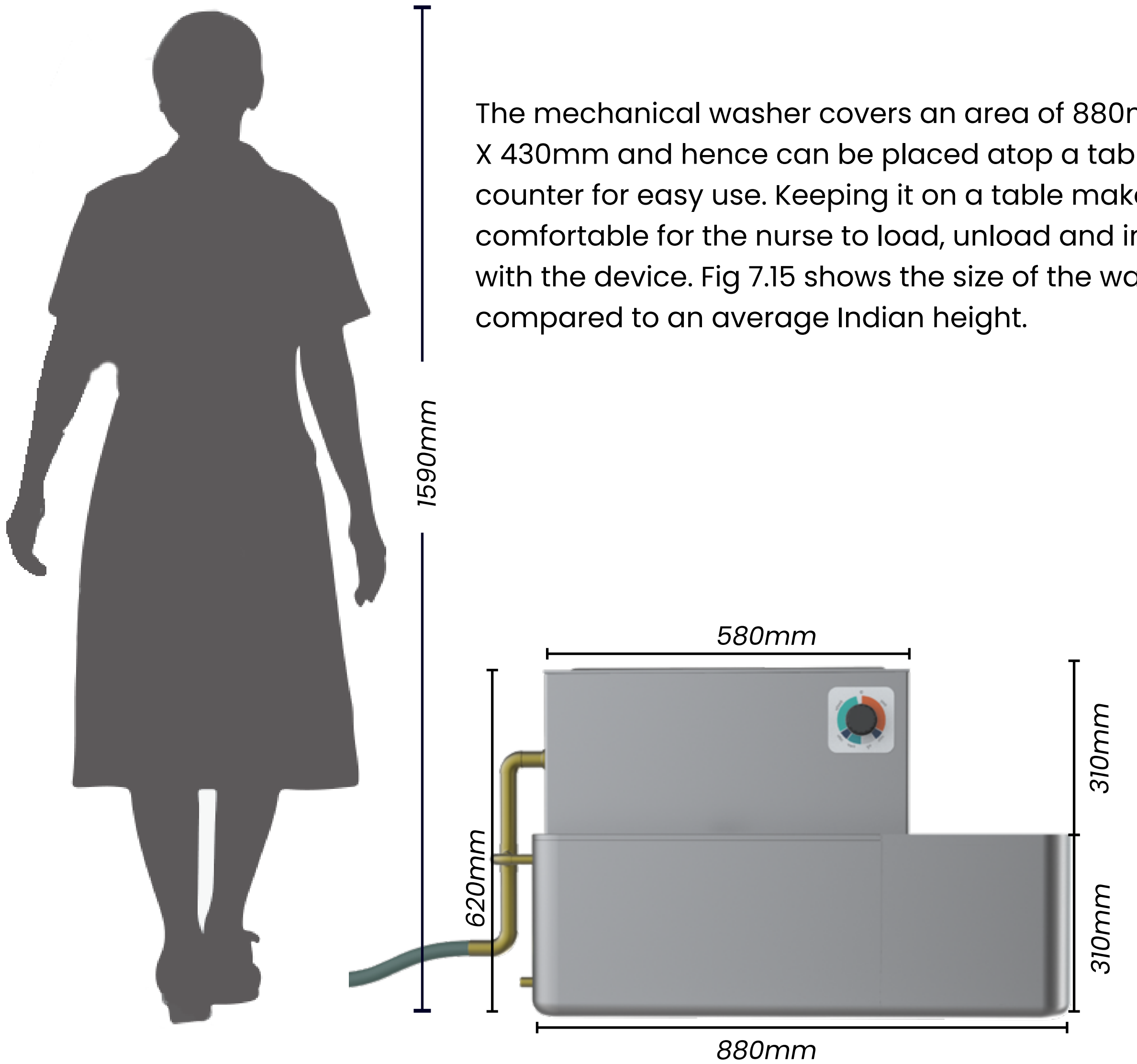


Fig 7.16 Scale of the frugal mechanical washer as compared to the average Indian height

The control knob is a single knob that spins 350º. The cycles are proposed to be pre programmed in such a way that the nurse's interaction with the control panel is minimum. Each batch completes washing in 30 minutes. The cycle is divided into six stages.

- Soaking : 10 minutes
- Draining : 2 minutes
- Brushing : 3 minutes
- Washing : 3 minutes
- Draining : 2 minutes
- Drying + UV-C : 10 minutes

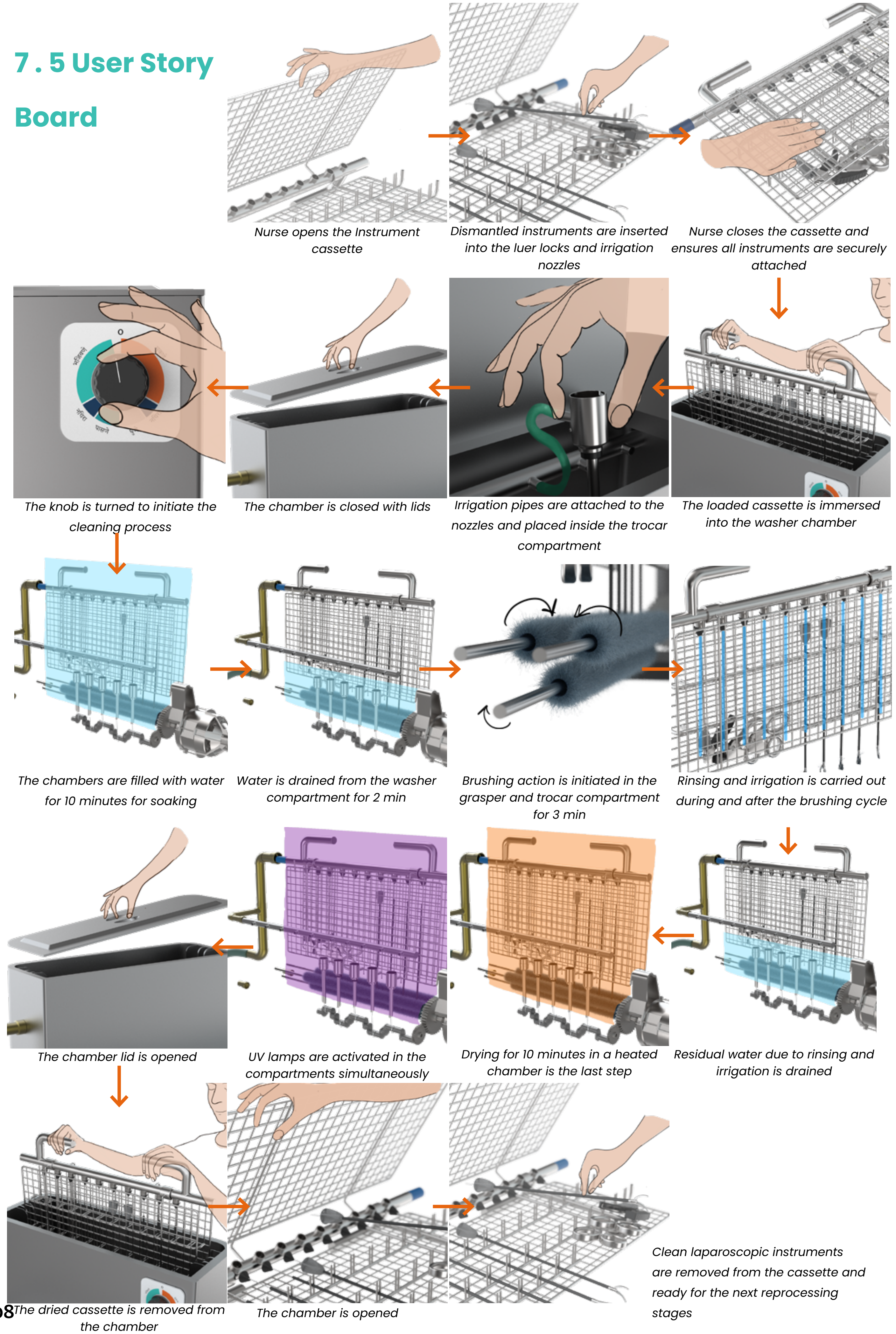
Total : 30 minutes

The illustration on the control knob is a sticker which can be printed in different languages to allow the locally employed nurses to interact with the device comfortably.

Fig 7.17 Control Knob in the Marathi script

Fig 7.18 Control Knob in the Kannada script

7 . 5 User Story Board



7 . 6 Envisioned Cleaning Journey

"the ""Envisioned Reprocessing Journey"" aims to be the new standard operating procedure for rural Indian hospitals"

The comparative study between rural Indian and High-Income hospital reprocessing journeys as mentioned in Chapter 4.4 shows the stark differences between the instrument reprocessing practices in both contexts by showing deficiencies in the rural Indian reprocessing procedure.

An "Envisioned Reprocessing Journey for rural Indian Hospitals" (fig 7.6.1) is created to suggest standardization of the reprocessing practices of laparoscopic instruments in the rural Indian context. This is done because no such standards are known to be followed and all rural hospitals have their own tweaks and practices. This journey is hence created keeping in mind the existing infrastructure in most rural Indian hospitals thus recognizing the steps missed from HICs.

The Envisioned journey aims to act as a middle ground between the long, expensive yet safe practices of HICs which is a Standard Operation Procedure (SOP), and the short, resource-constrained, and relatively unsafe practices of rural India. The "Envisioned Reprocessing Journey" aims to be the new standard operating procedure for rural Indian hospitals. Voids in the new journey form a basis for the final deliverable of this graduation project.

This chapter is dedicated to the explanation of this envisioned instrument reprocessing journey for rural India and is divided into five steps.

Collection

Pre Cleaning

Mechanical Cleaning

Sterilization

Storage

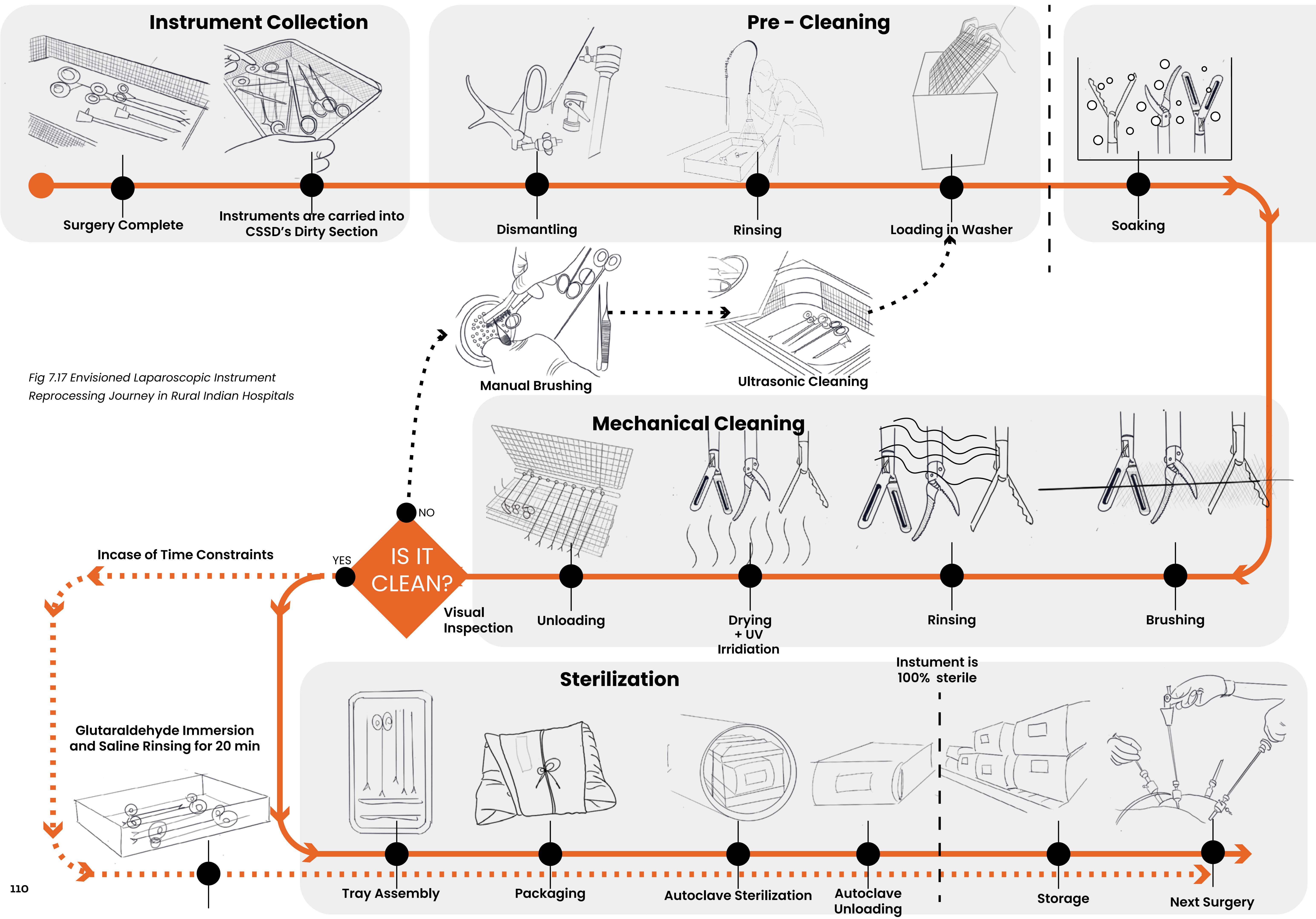


Fig 7.17 Envisioned Laparoscopic Instrument Reprocessing Journey in Rural Indian Hospitals

"The implementation of this washer early into the reprocessing practice reduces the nurse's exposure to pathogenic surgical instruments and takes the workload off the nurse"

1. Instrument Collection

Instruments collected and submerged in soaking trays directly after the surgery. This soaking prevents blood from drying on the instruments and prolongs their useful life.

2. Pre Cleaning

Cleaning is the most important step of the journey which precedes sterilization. The cleaning stage is characterized by the removal of pathogens, contaminants, and gross visible debris from the surgical instrument (Hariharan et.al 2018). This stage has been divided into 4 substeps: dismantling, rinsing, and loading in the washer.

The instruments when removed from the collection trays, still wet, are dismantled and rinsed under running water at room temperature. They are then directly loaded into the mechanical washer cassette where enzymatic soaking and brushing takes place mechanically. The implementation of this washer early into the reprocessing practice reduces the nurse's exposure to pathogenic surgical instruments and takes the workload off the nurse.

3. Mechanical Cleaning

Once the instruments are inserted in the mechanical washer, the chamber of the washer is filled with water to allow the instrument to soak for 10 minutes. The water is then drained away and the brushing cycle is initiated. Mechanical brushing action on the laparoscopic graspers and trocars removes surgical debris from hard to reach spots on these complex instruments.

Due to the containment of the instruments in a closed system, they can be efficiently brushed and washed with low dependence on the water as brushes have substituted impingement through water flow in this frugal automated washer.

The drying action with the help of the circulation of hot air inside the compartments is accompanied by Ultraviolet irradiation. This step thermally and spectrally destroys traces of pathogens. The instruments are now safe to be unloaded, handled without gloves, and visually inspected. The entire mechanical cleaning stage including soaking will take 30 minutes.

The provision of UV emitting lamps for visual inspection would potentially improve cleaning quality, outcome, and subsequent safety for hospital staff and patients. If traces of surgical debris are still visible on the instrument, they can then be manually brushed or ultrasonically cleaned. If the instruments are indeed free of surgical debris, they can be arranged in case trays and packaged for autoclaving.

4. Sterilization

The initial steps to the sterilization process include assembling the instrument trays and predetermined sets in surgical linens. Because this project only focuses on reusable laparoscopic instruments, all instruments can be packaged for conventional autoclaving. High pressure and high-temperature steam sterilization should yield ~100% sterile surgical instruments with no traces of surgical debris and contaminants.

During time constraints where the number of laparoscopic surgeries to be performed is high and instrument sets are lacking, disinfection in glutaraldehyde immersion followed by saline rinsing for 20 minutes could yield favorable results. This is because the foundational mechanical cleaning systems put in place have managed to remove a significant amount of surgical debris.

5. Storage

Ideally, the packed sterilized laparoscopic instruments should be stored in a clean and sterile environment awaiting surgery. At times when the laparoscopic instruments need to be sterilized faster, formalin tablets may be used if controlled, however, it must be avoided as much as possible to prevent hospital staff from its toxic fumes.

8 Evaluation & Validation

8 . 1 Evaluation

Evaluation of the concept is an integral aspect of the product design journey. Evaluations determine the functionality and feasibility of the concept design and demonstrate its proposed impact to the stakeholders. This section describes the various evaluation tests conducted showing the feasibility of the frugal mechanical washer for rural Indian hospitals.

8 . 1 . 1 Evaluation against Requirements

Through the concept design of the frugal mechanical washer, nearly most of the key product side and user side requirements have been fulfilled. The table below illustrates the requirements that have been fulfilled and reasons as to why some are not.

Through this concept design, the washer has been designed to be a standalone device that only depends on the hospital infrastructure for electricity to run the motors and water for rinsing. There are 10 luer lock nozzles with irrigation adapters that can clean 10 graspers at once and another compartment for flushing 5 trocars. The control panel is a simple knob which completes cleaning one batch in 30 minutes. This washer is designed to accommodate off the counter industrial grade brushes. Technical specifications were not available as vendors refused to present them. In the product side requirements, a cost analysis was not done due to lack of time.

In the user side requirements, it is not yet clear if the instrument cassette can be loaded within 5 minutes because a user test focused on loading is yet to be conducted.

#	KEY PRODUCT SIDE REQUIREMENTS
1	The washer should be a stand alone device with minimal dependence on hospital infrastructure.
2	The washer should be able to flush, wash and rinse the laparoscopic instruments.
3	The washer should wash laparoscopic instrument sets that consist of 10 graspers, 5 trocars, 1 set of basic surgical instruments and pipes.(fig 4.4.1)
4	The washer should have a separate provision for non lumened instruments and smaller attachments.
5	The washer should be able to rid the laparoscopic instruments of all gross bioburden mechanically.
6	The washer should have one main chamber with multiple smaller chambers for washing dismantled laparoscopic and ancillary instruments.
7	The washer should clean the laparoscopic instruments batch within 30 minutes.
8	The washer should be fully sealed to prevent splashing and aerosolization of soiled water.
9	Spare parts of the washer should be easily available and replaceable.
10	The washer should clean remove atleast 90% of the contaminants on each laparoscopic instrument.
11	The washer should not cost more than 600 Euro. (fig5.2.3)
12	The washer should use less than ~200L of water with evey batch.

#	KEY USER REQUIREMENTS
1	The loading of the instruments on the instrument rack should be simple, straightforward and quick.
2	The effort taken by hospital staff to load the loaded instrument rack in the chamber should be minimum.
3	The washer cart should be loaded within 5 minutes.
4	The washer should be operated with minimum interaction and vigilance from the hospital staff
5	The washer should be ergonomically feasible, taking into account average height of Indian females.
6	The washer control panels should be adaptable to local languages.

8.1.2 Testing and Stakeholder Validation.

Due to lack of time, it was not possible to build a 1:1 scale model of the frugal mechanical washer as displayed in the renderings in the previous section. Concepts born out of the brainstorm were hence tested for feasibility then implemented in the design which are mentioned in detail in Appendix G and Appendix H. Validation assessments were conducted with two methods: Performance Validation through physical prototyping and user validation through interview and feedback from a nurse in India.

1. Performance Validation.

A thorough test protocol was written and followed to test the efficacy of brushing action on contaminated laparoscopic instruments (see appendix H). By following the test protocol, cleaning the contaminated laparoscopic graspers with the triple brush arrangement provided consistent outcomes of clean laparoscopic graspers (fig 8.1.2). Microscopic images taken of the instrument provide visual proof of the cleaning efficacy of the setup (fig 8.1.1).

Trocars were also brushed in a similar method but with the help of oscillating brushes (Appendix G). The Performance validation for cleaning graspers and trocars with brushing has proven to be effective.

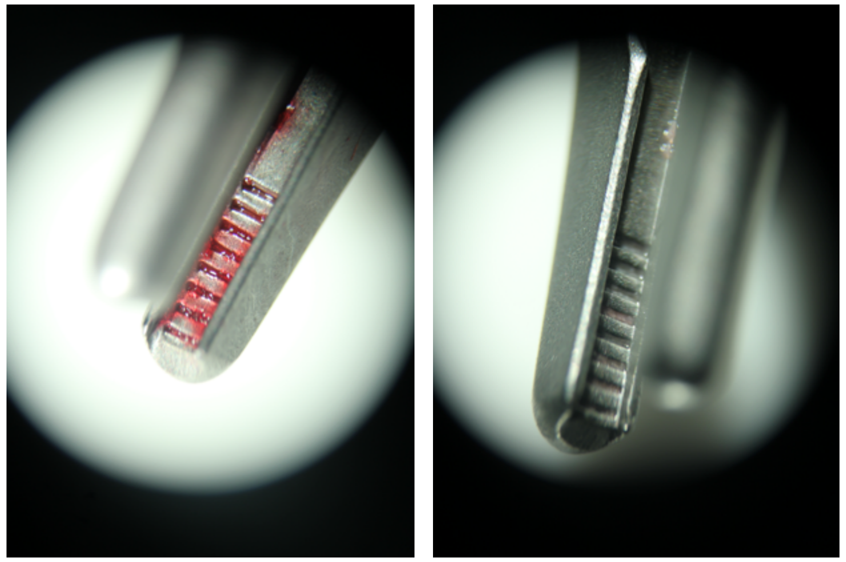


Fig 8.1.1 *Brushing action of double and triple brush arrangement seen under a microscope.*
—Left clip applicator after double rotor brush action
—Right clip applicator after triple rotor brush action

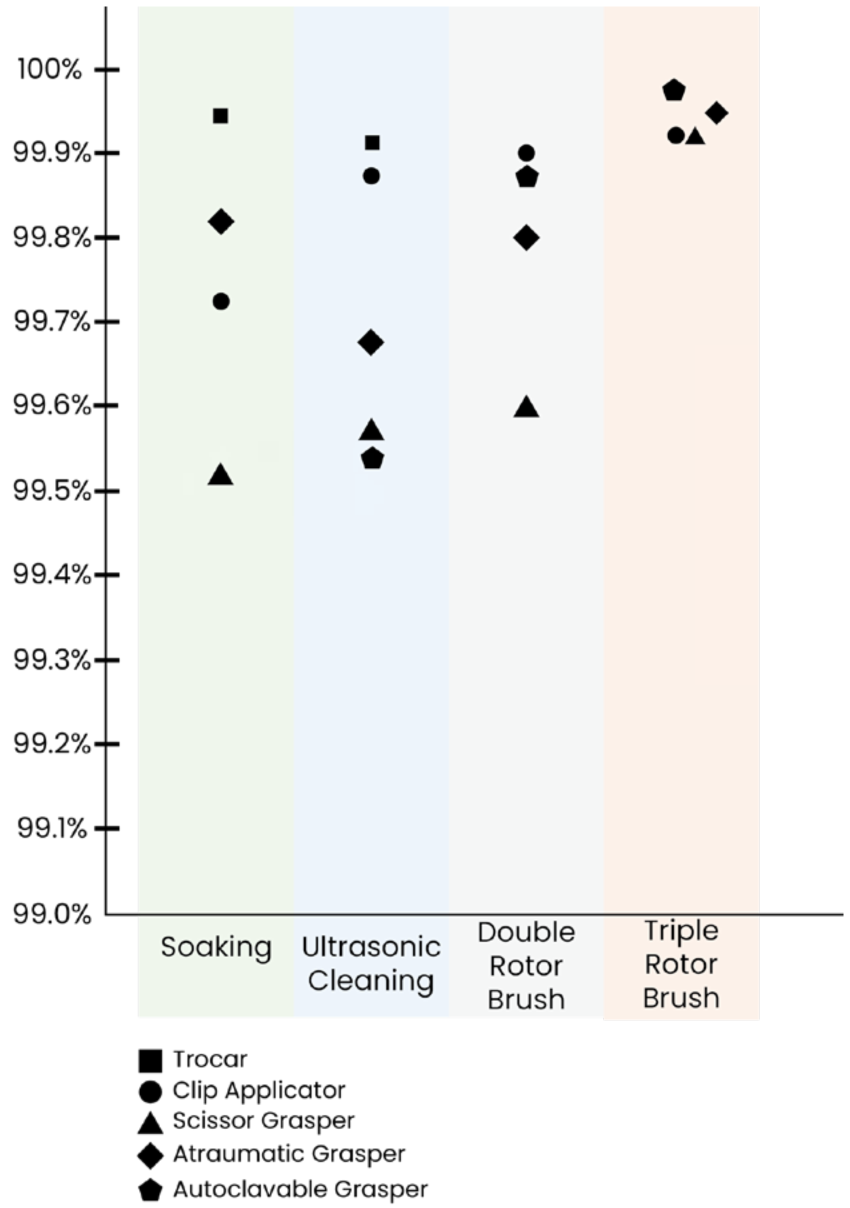


Fig 8.1.2 Amount of contaminants by weight removed by various cleaning protocols depicted in percentages.
—Cluster of instruments in the top right corner of the graph shows consistent outcomes in the coinciding brushing method.

2. User Validation

The primary users of this device are nurses in rural India. The COVID crisis made it difficult to contact multiple nurses. The feedback given by one rural Indian nurse is taken into account for the user validation.

An interview with a highly experienced nurse in the field of low resource healthcare was conducted through video conferencing. The design renderings of the frugal mechanical washer, its storyboard, and features were presented.

The topic of discussion was the user interaction between the nurse - cassette and the nurse - control panel. The cassette system was found to be user friendly and easy to understand at the first glance. He expressed concerns in terms of attachment of the instruments into the irrigation nozzles. The idea of using rubber sheaths to accommodate a variety of instrument diameters settled the concern. The mechanism of interlocking bristles of brushes spinning into each other was well received.

The control panel was found to be easy to understand as the larger segments like soaking and drying meant longer cycle times as compared to brushing and draining. Because most cleaning devices are made of stainless steel to avoid corrosion, the nurse agreed that stainless steel is a preferred material for the washer body and cassette.

Further, in terms of functionality, it was noted that the frugal washer must incorporate entire instrument sets of specific surgeries to be cleaned together. Certain laparoscopic surgeries demand larger instruments. It was noted that a provision for these instruments should also be considered. To prevent pathogenic, detergent, and mineral buildup inside the compartments, a regular self-cleaning cycle was suggested.

The overall design was received very positively and he expressed excitement and happiness after the discussion.

"this is a new concept and very innovative"

-nurse during the interview

9 Recommendations & Conslusion

9.1 Recommendation

The goal of this MSc Graduation Project was to conceptualize and design a frugal mechanical washer to clean laparoscopic instruments in rural Indian hospitals which has been achieved and discussed in chapter 7. However, in order to implement this device in reality, certain recommendations and design alterations are yet to be implemented. This section explores the recommended design alterations to be taken into account to make this product successful.

1. Crankshaft mechanism for the Trocars.

The crankshaft used in this concept design is custom made for this application only. Crankshafts of this size, shape, and specifications are not available in existing products. Hence, harnessing a spare crankshaft from other products is not possible. There is hence a requirement for a universal method to internally brush multiple trocars simultaneously with parts that can be easily manufactured or procured.

2. Ultrasonic Cleaning.

Ultrasonic cleaning is a powerful yet untapped method of cleaning delicate and complex surgical instruments in rural India. Implementation of ultrasonic cleaning systems in this frugal mechanical washer compartment could greatly enhance the efficacy of the device and promise consistent results. It is hence recommended to implement an ultrasonic apparatus inside the compartments of this device.

3. Brushing the insides of long lumened instruments.

The current design solution focuses on brushing the grasper's hinges, grasper jaws, and the insides of the trocar. The long and hollow laparoscopic instruments like the clip applicators and grasper handle also need to be brushed from the inside. It is hence recommended to modify this frugal mechanical washer to implement mechanical brushing systems to brush the insides of the lumened instruments.

4. Self-cleaning of the compartments and pipes.

The washer chamber itself demands periodic cleaning. Regular use increases the occurrence of biofilm accumulation on the compartment surface. The slender pipes and irrigation tubes get clogged due to detergent clumps and hard water buildup. Periodic self-cleaning cycles should be implemented in the programming of the mechanical washer.

5. Glutaraldehyde Disinfection.

The use of a 2% glutaraldehyde solution for disinfecting and sterilizing surgical instruments is a common practice in rural India. This solution is known to release mildly toxic vapors. Also, the immersion time of instruments in this solution is not properly followed. It is recommended that an extra step of glutaraldehyde immersion and rinsing could increase the frugal mechanical washers' functionality, efficacy, and reduce the nurse's exposure to toxic fumes and maintain proper immersion time.

6. Cleaning larger MIS instruments.

This mechanical washer has been designed to service a basic set of laparoscopic instruments i.e conventional graspers, clip applicators, and trocars. Other minimally invasive surgical instruments like Uretro Renoscopes are larger and longer than conventional MIS instruments. It is recommended to have a provision to accommodate such instruments for further development of this washer.

7. Water filtration.

To maintain the efficacy of enzymatic detergents, the health of the washer plumbing, prevent deposition on the dried instruments, reverse osmosis deionized water is used. There is a lack of standardized quality of water in rural India and mineral content is high. It is recommended to implement freshwater filtration systems to soften the water for the best washing and rinsing results.

In rural regions, wastewater disposal is a major problem accounting for the spread of diseases when untreated water is disposed of. Similar to a filtration system on the water inlet side, having a filtration system for drainage is equally important. This drainage system should trap surgical deposits and neutralize pathogens before the wastewater is disposed of.

8. Ultraviolet irradiation.

To kill viruses and traces of microorganisms, implementing UV-C radiations inside the washer chamber can add disinfectant to the list of functionalities in addition to mechanical brushing and rinsing. It is recommended to include UV-C emitters into the washer compartments and implement it simultaneously to the drying stage.

9. Recirculation Piping

Recirculation systems are recommended to be implemented in the washer drain to reduce the dependence on freshwater for the rinsing cycles. This can significantly cut water use.

10. Testing

Testing with existing washer-disinfectors used in high-income hospitals was not conducted due to restrictions in Dutch hospitals due to COVID-19 safety protocols. Brushing tests mentioned in Appendix H should be conducted in more controlled environments.

9 . 2 Conclusion

The end result of this MSc Graduation project is a concept design for a frugal mechanical washer for rural Indian hospitals. Subsequently, an Envisioned Laparoscopic instrument reprocessing journey designed for the placement of this washer has been created. This frugal mechanical washer is designed to produce repeatable outcomes in providing clean and debris free laparoscopic instruments and alleviate the rural Indian nurse's workload and restore safety against HCAIs.

The research phase consisting of literature reviews, field visits, observations, and analysis of laparoscopy, laparoscopic instruments, and reprocessing practices in rural India showed a severe lack of proper methods and guidelines being followed. This hampered the outcomes of having clean and sterile instruments. This design is set out to disrupt the existing reprocessing practices in rural India by being the first version concept of a washer that implements a different technology for providing the same outcomes like that in high-income hospitals. Through a series of extensive tests friction has proven to be a powerful method of cleaning laparoscopic instruments. The concept simply substitutes the fluid shear stresses induced by high volumes of flowing water with friction through brushing. This design very successfully caters to most of the requirements mentioned in the list of requirements.

The methods used in the ideation phases of the project were inspired from the Delft Design Guide. The Double Diamond framework has been extensively used to systematically map out the project phases. For the idea generation phases, methods like the morphological charts, SCAMPER and How To's were generously implemented. The discovery phase was where brainstorm sessions and creative facilitation sessions brought forth a plethora of ideas from a wide variety of participants. Testing these ideas is a significant aspect of this graduation project. Through the resources available in the applied lab of the TU Delft, Faculty of Industrial Design Engineering, new test protocols were designed to properly justify which concept feasibility. Implementation of the Harris Profile helped select the most feasible ideas from the brainstorm. Clustering the various facets of mechanical washing of surgical instruments, loading, flushing and washing was indeed a systematic approach that helped identify the problems in better detail. Generating a final product was similar to playing lego where individual ideas were pieced together. Defining the design drivers imbibed the values the final design must display.

The frugal mechanical washer for rural Indian hospitals is conceptualized so as to be built with integrating components and parts from local or national manufacturers to enhance the repairability and usability of the device. In terms of functionality, this device disrupts the existing practices of instrument cleaning in rural India by implementing most of the manual process mechanically into itself. Interaction between nurse and surgical instruments are hence considerably reduced. The entire washer demands no more than 0.30squaremeter thus reducing the device's requirement for space. The approximate volume of water this device demands is ~125L per cycle which is 75L less than existing high-income washer-disinfectors. This reduces the demand for high volumes of water in rural India where scarcity and unreliable water supply is a real concern. Further tests are required to fully substantiate this claim.

It is important to note that a comprehensive cost analysis was not conducted due to lack of time. It is highly recommended to perform a cost analysis to give an approximate value of this device.

In summary, this graduation project has aimed and successfully addressed a very basic and grassroot level problem. Surgical safety in LMICs is indeed an under-addressed problem who solution is as simple as maintaining and using clean surgical instruments. Laparoscopy in rural India is booming, but so are the rates of morbidity. By simply using clean laparoscopic instruments, the morbidity statistics are bound to plummet. It is hoped that implementation of such a device in rural hospitals will save countless lives by curbing the instances of surgical site infection in all of Rural India.

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